



Computerizing clinical practice guidelines

Guidance in clinical work practice and implications for computerization

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PhD thesis

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Computerizing clinical practice guidelines

- Guidance in clinical work practice and implications for computerization

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Preface

This thesis is submitted to obtain the PhD degree at the department of Computer Science, Faculty of Science at the University of Copenhagen. The work described in the thesis was carried out between February 2007 and March 2010.

I have a long-standing interest in improving the quality of care. Originally, I was educated as a certified surgeon, in departments where the issue of measuring and constantly improving the quality of care were high on the agenda. Further, I have been working with improvement of postgraduate medical training from the perspective that well educated professionals are a prerequisite for high quality of care. I have pursued my interest in quality of care by supplementing my medical education with a master's degree in business management (*HD i organisation*) and a master's degree in health informatics.

In 2007 I found the time ripe for thorough studies of how information technology could be applied as a vehicle for improving quality of care. I was lucky that a PhD scholarship was established in cooperation between the IT-University (ITU) of Copenhagen, the IT-company Resultmaker and the Ministry of Science, Technology and Innovation. I originally started my PhD studies at ITU, but in spring 2008 Finn Kensing, my primary supervisor, was offered a post as Director of Centre for IT-innovation (CITI) at the University of Copenhagen, and I decided to follow him.

Acknowledgements

I would like to express my gratitude to all who have been supporting and challenging me in the work with this thesis. First of all, thank you to my two supervisors, Finn Kensing and Thomas Hildebrandt from the ITU, for guidance and inspiring conversations on my way into the research area.

I would like to thank the staff at the oncology clinics in the Capital Region of Denmark for their cooperation and patience during the observation studies and workshops. Thanks also to Lars Rune Christensen, my fellow PhD student, who took part in the observations and collection of data, and to Birgitte Seierøe Pedersen and Morten Jørgensen who helped validating the findings from the observation studies.

Thanks to Inger Dybdahl Sørby and Øystein Nytrø for inviting me to the Norwegian University of Science and Technology (NTNU), Department of Computer and Information Science (IDI), and the Norwegian Centre for Electronic Patient Records (NSEP), where I did my exchange programme for four inspiring months in the spring 2009. Thanks also to all the good colleagues and friends I got to know there and for the thoughtful and reflective discussions we have had on health informatics.

I am grateful to have been invited to the Department of Bio-Medical Informatics at the University of Pavia and to Knappschaft Krankenhaus in Bottrop, where I was given a stimulating insight in how computerization of clinical practice guidelines can be carried out.

Thanks to Birgitte Seierøe Pedersen, Kirsten Ann Jeberg, Christian Koerner and Claus Balslev, my master students from ITU, who made the first CardioData prototype as part of their master project in a rewarding cooperation with many committed professionals at the Danish Institute for Medical Simulation (DIMS) at Herlev Hospital.

Thanks to all the members of the HIT group, for inspiring discussions and feedback in workshops and else where.

Thanks also to my family and friends for continuous love and support and occasional sharp remarks on my continuous studies.

Last, but not least, I thank my husband Lars for patience, help and support in all imaginable ways.

Karen Marie Lyng,
October 2010

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Abstract

It is well described that hospitals have problems with sustaining high quality of care and expedient introduction of new medical knowledge. Clinical practice guidelines (CPGs) have been promoted as a remedy to deal with these problems. It is, however, also well described that application and compliance with CPGs in most areas of clinical practice are deficient. Computerization of CPGs has been brought forward as a method to disseminate and to support application of CPGs. Until now, CPG-computerization has focused on development of formal expressions of CPGs. The developed systems have, however, not gained any extensive application in clinical practice. The basic assumption in this thesis is that the scanty penetration is due to an inappropriate design process when designing computerized CPGs for clinical work practice.

This thesis examines the application of guidance within areas where CPG compliance is known to be prominent in order to determine demands on clinical guidance and characteristic features of applied guidance. The contributions of this thesis fall in two main areas:

- An analysis of how guidance is applied in clinical practice, within areas where CPG compliance is known to be high. The analysis focuses on the emergence of general clinical work practice demands on guidance
- An analysis of guidance demands from clinical work practice and business strategy, focusing on implications for the design of computerised CPGs.

In my research, I have applied observation studies, interviews, workshops and collection of guiding artefacts and CPGs as methods for obtaining data. In the analysis of data, a grounded theory approach was applied. Further prototyping was applied to validate and refine the findings, and finally two clinicians validated the results.

The empirical basis of the thesis is comprised by fieldwork in three oncology departments and a case study of advanced life support. Although close to all patients within oncology are treated according to a CPG, I found limited application of physical CPGs and web-based CPG portals. However, I found comprehensive application of activity specific pre-printed forms and standard order sets embedded in the work practice and presenting guidance at the point of care. I have conceptualised the forms and standard order sets as second order guiding artefacts. Second order guiding artefacts were transformed from primary guiding artefacts (protocols and CPGs) according to a standard operating procedure. Based on a participatory design approach, prototypes for computerization of CPGs have been developed and applied for clarification of demands on computerized CPGs.

The clinicians in my studies expressed a desire to have computerised CPGs, although it was a prerequisite that they should be easy to apply and not demand interruptions in clinical work.

Based on my research, I found that computerized clinical guidance should be:

- Activity specific
- Present at the point of care
- Embedded in work practice
- Flexible
- A source for coordination
- Automated when feasible
- Designed in a way that provides room for local adaptations of guidance
- Designed with focus on specific business strategic aims

Further, based on my findings, I will suggest that design of computerized CPGs should be based on: 1) scrutinization of the clinical work practice, 2) articulation of the business strategic aims, and 3) analysis and formalization of CPGs. This will imply orchestration of design teams with competencies from a wide array of disciplines such as health practice, business management, knowledge management and information systems.

1 Introduction

This thesis is dealing with establishing demands on computerization of clinical practice guidelines (CPGs) to support application of and subsequent compliance with CPGs in clinical work practice. My research sets out to examine the demands on clinical guidance in hospitals, focusing on the implications for potential computerization. Before summarizing the contributions made, the background for the thesis is outlined.

Background

Until the beginning of the 1970s, it was generally assumed that the professionalism¹ of clinicians² guaranteed quality of care. In 1971, Archie Cochrane published "Effectiveness & Efficiency - random reflections on health Services" (Cochrane, 1971 reprint 1999). This book together with a paper by Wennberg and Gittelsohn, "Small Area Variations in Health Care Delivery" published in Science 1973 (Wennberg J and Gittelsohn, 1973), made it obvious that professionalism in itself did not guarantee high standards or prevent unintended practice variation. Numerous publications followed confirming that problems with unintended practice variation and quality of care are ubiquitous (Chassin and Galvin, 1998, Wenneker and Epstein, 1989, Settnes and Jorgensen, 1996, Kohn et al., 2000, Schiøler et al., 2001). Concurrently, it was realised that the knowledge base regarding effective medical care continues to improve, while clinical practice continues to lag behind, and errors occur with distressing frequency (Davis et al., 2006, Lugtenberg et al., 2009, Kohn et al., 2000).

This has lead to a substantial focus on developing methods for sustaining and improving quality of care³ in clinical practice (Committee on Quality of Health Care in America, 2001). CPGs have been – and still are – a cornerstone in this work. According to the American Institute of Medicine (IOM), CPGs can be defined as "*systematically developed statements to assist practitioner and patient decisions about appropriate health actions for specific clinical circumstances*" (Field and Lohr, 1990). CPGs are developed within all areas of health care and for all clinicians within all medical specialties. Development of CPGs is taking place at various organizational levels, from small local units to multinational bodies.

It is, however, well known that adoption of CPG recommendations in clinical practice is slow (Lomas et al., 1993) and that clinicians' compliance with CPGs are deficient (Cabana et al., 1999, Quaglini, 2008, Panzarasa et al., 2007, Jami et al., 2007). Further, it has been shown in a recent Cochrane review that printed CPGs have only a limited effect on quality of care (Farmer et al., 2008). There is no coherent theory explaining why it is so difficult to achieve CPG compliance in clinical practice. It is, however, known that there is a wide variety of barriers, including lack of awareness, lack of time for CPG consulting, lack of familiarity, lack of agreement, lack of outcome expectancy and inertia of previous practice that prevent implementation (Cabana et al., 1999, Haines et al., 2004, Wensing and Grol, 2005a).

CPGs have traditionally been implemented through passive diffusion, although it is well documented that passive diffusion is not a very expedient strategy (Rogers, 1995, Rogers, 2002, Bradley et al., 2006). Accordingly, the implementation strategy - though prominent - has

¹ "Professional" or "health professional" is used in the same way as Mintzberg MINTZBERG, H. (1993) *Structure in fives - Designing effective organizations*, Prentice Hall, Englewood Cliffs NJ 07632. referring to members of a professional community trained according to standards set outside the organisation of the employee. According to Mintzberg standardisation of skills is a major coordination mechanism in professional organizations

² "Clinicians" is used as a collective term in the same way as Coiera COIERA, E. (2003) *Guide to Health Informatics*. Hodder Arnold, London, second edition., referring to any healthcare practitioner - physicians, nurses and other allied health professionals – directly involved in patient care

³ Quality of care is often defined as being constituted of: safety, effectiveness, patient-centeredness, timeliness, efficiency and equitability COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA (2001) *Crossing the Quality Chasm: A New Health System for the 21st century.*, Washington, DC, National Academy press.

not proven to have any major impact on clinical practice (Dearing, 2008, Sheldon et al., 2004). There are numerous theories on why this is so, but none of them are applicable in all circumstances (Rogers, 1995, Smith, 2000, Oxman et al., 1995, Grimshaw et al., 2004). Due to the lack of a coherent theory for how to overcome the barriers, many authors recommend a multi-facetted approach for implementation of CPGs (Weinert and Mann, 2008, Cochrane et al., 2007, Prior et al., 2008, Grol, 2005a, Wensing and Grol, 2005b). A multifaceted approach implies a combined application of two or more intervention strategies to implement change. A multifaceted strategy for implementing CPGs may be based on various theories, such as learning theories, cognitive theories, social learning theories or theories on organizational culture (Grol, 2005c). The various theories imply a large toolbox of methods for implementing change, where some of the methods may be overlapping. Computerization of CPGs may be included in several of the change strategies: as a way to educate the individual clinician in an education theoretical approach (Wensing and Grol, 2005a), as a change agent in a social network theoretical approach, or as a method to induce organizational learning (Grol, 2005c). Further, as hospitals are presently experiencing a wide-scale introduction of clinical IT computerization, CPGs is an obvious new facet in a multi-faceted implementation strategy (van Merode et al., 2004, Häyrynen et al., 2008).

Several paradigms exist for computerization of CPGs. The most common paradigms are: (1) as part of a multifaceted CPG implementation strategy (Dufour et al., 2006, Garg et al., 2005), (2) as part of configuration of clinical IT systems (Häyrynen et al., 2008, van Merode et al., 2004), or (3) as the foundation for developing and introducing business process management systems within healthcare (Mulyar et al., 2008b, van der Aalst and Pesic, 2006). Irrespective of the paradigm, all present computerizations of CPGs have focussed on developing formalisms for presentation of CPGs – more than 15 formalizations have until now been published (Isern and Moreno, 2008, de Clercq et al., 2008, Mulyar et al., 2008b, Peleg, 2007, Jenders, 2007, Aigner et al., 2008). Computerization has been accomplished at various levels of automation (Cummings, 2004). At the most basic level, storage and search facilities for CPG documents in knowledge management systems are provided (Larson, 2003). On a more advanced level, there are computer interpretable guidelines (CIG) (Peleg et al., 2001, Eriksson et al., 2005, Isern and Moreno, 2008). On the most advanced level, computer executable guidelines (CEG) can be found (Isern and Moreno, 2008)(de Clercq et al., 2008, Eriksson et al., 2005, Peleg et al., 2003). Most have focussed on some kind of workflow, although computerization of CPGs may also be in the form of reminders and alerts (Bates et al., 2003).

Even though there are significant examples of computerization of CPGs that have proven to have a beneficial effect on process outcome (Bates et al., 2001) as well as on patient outcome (Kawamoto et al., 2005, Quaglini et al., 2004), the systems have not gained any wide-scale application in clinical practice. This is so even though there has been much managerial focus on the introduction of clinical IT as a tool for improving quality of care (Committee on Quality of Health Care in America, 2001, Aarts et al., 2007, Lenz and Reichert, 2007).

My basic assumption is that the scanty penetration is due to an inappropriate design process when designing computerized CPGs for clinical work practice. A reason for the application problems may be that so far design of computerized CPGs mainly has been accomplished from a technology perspective rather than from a clinical work practice perspective. Although formalization of CPGs is a prerequisite for computerization, formalization in itself does not ensure application of the computerized CPGs. Therefore, there is a need for exploring the demands on guidance from the clinical work practice, and the business strategy, and to include fulfilment of these demands in the design of computerized CPGs. In this way, several of the potential barriers to CPG and clinical computer application can be addressed in the design process.

Research questions

In spite of the complexity inherent in dissemination and implementation of CPGs and in the development and deployment of clinical IT in hospitals, my hypothesis in this thesis is that most of the problems with penetration of computerized CPGs in clinical practice are due to an inappropriate design process. Thorough determinations of demands based on meticulous examination of work practice and business strategy should constitute the first steps in the design of computerized CPGs. Therefore the research questions that this thesis sets out to examine are:

RQ1: How is guidance applied in clinical work practice?

RQ2: What kind of demands do clinical work practice and business strategy put on computerization of clinical practice guidelines?

Limitations

The thesis is not dealing with the legitimacy of CPGs, although it has regularly been discussed in health professional forums (Mead, 2000).

Nor will it deal with CPG development, although it is known that problems with ambiguity and internal validity have implications on the computerization of CPG (Codish and Shiffman, 2005, ten Teije et al., 2006). Some authors even recommend a parallel CPG development and formalization/ computerization process (Goud et al., 2009).

According to the applied CPG definition, CPGs may address both clinicians and patients. However, I have only addressed CPGs in relation to clinicians within hospitals. CPGs are developed for all professional groups within healthcare. Most of the literature is, however, either addressing all professional groups in general or physicians specifically; the same goes for this thesis.

2 Reflections on CPGs

The current emphasis on evidence-based medicine (EBM) and evidence-based clinical practice has promoted CPG development and made CPGs a prominent topic in the debate on quality of care. There is a continuously ongoing debate on CPGs in the health professional literature, reflecting that CPGs are a controversial and continuously evolving concept (Garber, 2005, Boyd et al., 2005, Mead, 2000). I will touch upon some of the major trends in the debate in this chapter.

The concept of CPGs is covered by many terms⁴. CPGs are often being used interchangeably with protocols (Rosenbrand et al., 2008). Several attempts have been made of defining the concept. The key focus in the definitions varies between origin, development method and purpose of the CPGs:

- *“Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health actions for specific clinical circumstances”* (Field and Lohr, 1990)
- *“We define clinical practice guidelines as user-friendly statements that bring together the best external evidence and other knowledge necessary for decision-making about a specific health problem”* (Sackett et al., 1998) p.112.
- *“Practice guidelines: official statements from organizations and agencies regarding the appropriate use of procedures and treatments.”*(Woolf, 2000) p. 364.
- *“Guidelines are a way to translate research results and clinical experiences in practice into recommendations about care procedures”.* (Grol, 2005b) p.2.
- *Guidelines are collections of practical information that assist with clinical decision making. Evidence-based guideline development includes a critique of the quality and an evaluation of the strength of the published evidence”* (Hanson et al., 2008) p.184.
- *“CPGs outline a plan of expected care, providing a guide to recommended practice and outlining the likely outcomes of care. They provide a guide to best practice, a framework within which clinical decisions can be made, and are used as a benchmark against which clinical practice can be evaluated. Historically, CPGs were often developed by consensus of a group of expert clinicians without explicit reference to research evidence. Evidence-based CPG development emphasises the importance of linking recommendations to the scientific research that supports them, identified through a rigorous systematic identification and appraisal of all relevant research”* (Turner et al., 2008) p. 2.

Although the definition by Institute of Medicine (IOM) (Field and Lohr, 1990) is the oldest, rather broad and not very specific, it is also the most widely applied (Eccles and Mason, 2001, Vlayen et al., 2005, Andrews and Redmond, 2004) and somehow the most operational, and therefore the one I have chosen to apply in this thesis.

There has been a strong debate on the feasibility of CPGs within the health professional communities (Berg, 1997, Mead, 2000). Advocates of CPGs argue that CPGs will enhance quality of care, reduce unwanted variations and render medical practice more scientific. Critics on the contrary argue that CPGs will lead to cookbook medicine, de-skilling of clinical competencies and reduced quality of care (Berg, 1997). Cut to the bone, a major substance in this debate on application of CPGs was on coordination mechanisms; the professional bureaucracy where standardization of skills is the key coordinating mechanism versus the machine bureaucracy where standardization of work is the key coordination

⁴ In Denmark there are at least 8 terms covering the whole or parts of the CPG concept: kliniske retningslinjer, kliniske vejledninger, kliniske instrukser, faglige politikker, referenceprogrammer, standardbehandlingsplaner, protokoller, kliniske procedurer. The terms may further be mixed in various ways.

mechanism (Mintzberg, 1993). The current interest in CPGs has moved away from discussing the legitimacy of CPGs, to examining the effect that has, however, turned out to be dubious (Lugtenberg et al., 2009, Farmer et al., 2008).

Publication of CPGs has also become a vector for several other agendas, as CPGs are being published by various actors for various reasons, for example:

- As a tool for clinical managers to regulate quality of care and avoid errors and unintended variations (Weisz et al., 2007)
- As a tool for administrative managers to support efficiency and cost cutting of clinical work (Weisz et al., 2007)
- As a method for professional societies to consolidate professional autonomy (Weisz et al., 2007)
- As a way for clinicians to deal with the continuous growth in medical knowledge (Davis et al., 2006)
- As a prerequisite for hospital organizations for obtaining accreditation by an accreditation body (Joint commission – www.jointcommission.org, last accessed October 2009)

The differences in scope and variety of stakeholders have led to a variety in CPG expressions. This may be a reason for some of the problems with ambiguity and validity of CPGs (ten Teije et al., 2006). The validity problems can be referred to several issues. Firstly, invalidity of medical content may be caused by outdated knowledge (Shekelle et al., 2001, Shojania et al., 2007). Secondly, current CPGs are addressing human beings that are capable of coping with ambiguities, inconsistencies and logical errors in the expressions (Goud et al., 2009). Thirdly, the syntax applied by various CPG authors may differ substantially, leaving room for interpretation (Peleg et al., 2001). The validity problems are a major issue that have to be dealt with when computerizing CPGs, even though guideline authors are encouraged to employ rigorous formal techniques, to ensure medical, logical and syntactic validity of CPGs (ten Teije et al., 2006). Several international governing organizations like the Guideline International Network (GIN)⁵, International Society on Quality in Healthcare (ISQUA)⁶, the AGREE collaboration⁷ and, the Cochrane collaboration⁸ have been established. The aim of these organisations is – in cooperation with national bodies – to develop standards for CPG development and assessment of CPG outcome (Turner et al., 2008).

It is frequently emphasised that CPGs should be based on a critical appraisal of the best existing scientific evidence, preferably based on randomized controlled trials (RCT) (Atkins et al., 2004, Guyatt et al., 2008, Sackett et al., 1998) and that the recommendations should be graded to reflect the strength of the evidence base (Schunemann et al., 2008). Substantial differences in evidence-based CPG recommendations on the same well-defined clinical entity can, however, be found (Christiaens et al., 2004). Differences may be caused by varying focus, such as patient safety, scientific evidence, patient centeredness (Christiaens et

⁵ The Guidelines International Network (G-I-N) is an international not-for-profit association of organisations and individuals involved in the development and use of clinical practice guidelines. (<http://www.g-i-n.net/index.cfm?fuseaction=about>)

⁶ The International Society for Quality in Health Care (ISQUA), is a non-profit, independent organisation. ISQua works to provide services to guide health professionals, providers, researchers, agencies, policy makers and consumers, to achieve excellence in healthcare delivery to all people, and to continuously improve the quality and safety of care. <http://www.isqua.org/>

⁷ AGREE is an international collaboration of researchers and policy makers who seek to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment. appraisal of guidelines research and evaluation – (<http://www.agreecollaboration.org/>)

⁸ The Cochrane Collaboration is an international not-for-profit and independent organization, dedicated to making up-to-date, accurate information about the effects of healthcare readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. The major product of the Collaboration is the Cochrane Database of Systematic Reviews which is published quarterly as part of the Cochrane Library (<http://www.cochrane.org/>)

al., 2004) or be due to cultural differences (Eisinger et al., 1999). Another discussion outside the scope of this thesis is the transmission of results of a RCT in a population to an individual that may or may not be a member of the population or might be one of those X% that are not supposed to benefit from the intervention. This problem area is often brought forward as an explanation for non-compliance with CPGs (Cabana et al., 1999).

Guidance in CPGs can be divided into different types of guidance: decision support (Greenes, 2007, Buchtela et al., 2008), process support (van der Aalst et al., 2009, ten Teije et al., 2008), documentation support (Bernstein and Andersen, 2008, Lyng and Kensing, 2008, Steichen et al., 2007) and task support (Essaihi et al., 2003). Decision support aims at matching the specific clinical circumstances as reflected in conditions, preconditions and the aim for post-conditions with appropriate actions. Process support provides a presentation and sequence of recommended activities for specific circumstances. Documentation support provides information on recommended documentation and may include documentation templates. Documentation templates may indirectly serve as decision and/or process support as demands on documentation of specific actions entail that the action should be executed. Task support provides detailed recommendations on how to perform a specific action. The various types of guidance are, however, frequently intermixed in any individual CPG, and the various types of actions are closely intermingled in clinical work practice. The background to some CPGs is a disease or condition, while the background to others is a task or process. Some CPGs are addressing a single profession, while others are addressing multiple professions that may have different cognitive practice models (Johnson and Turley, 2006) and cultures (Eriksen and Ulrichsen, 1991). These differences may also be reflected in different perceptions of CPGs (Lyons et al., 2005).

The fact that patients with multiple chronic conditions are a large and growing segment of the population may cause confusion in connection with the application of CPGs (Vogeli et al., 2007). Hence application of CPGs in case of comorbidity may entail contradictions in recommendations (Boyd et al., 2005).

Most literature on implementation of CPGs advocates an 'implementation of change' perspective (Grol et al., 2005, Trivedi et al., 2009, Prior et al., 2008). This reflects that numerous CPGs are published as a method for translating research results into new recommendations on appropriate health care, entailing change of previous practice. CPGs may, however, also be published as an articulation of existing standards or as a method for presenting "appropriate health actions" for specific rare clinical circumstances. In the latter cases, CPGs serve as a tool to preserve health care, and change theories may not be of much help. It has been published that the time for CPGs to be adopted in routine practice is approximately five years (Lomas et al., 1993)

The above-mentioned paradigms and problems reflect that CPGs are a heterogeneous concept reflecting the complex knowledge base, organizational structures and processes within hospitals. The problems and challenges have to be dealt with when computerizing CPGs.

Relevance for this thesis: In this thesis, I have worked with already existing and clinically applied CPGs within oncology and in relation to advanced life support (ALS). The examined CPGs have been developed by health professionals as tools for regulating quality of care, avoiding errors and unintended variations and supporting continuous monitoring and development of quality of care. Application of protocols has become profoundly integrated in the oncology specialty (Keating and Cambrosio, 2007), where it has become common practice that research protocols are undergoing adaptation to standard treatment protocols, when the research project is over and the research protocol has proven superior to previous practice. By doing my research in an area where CPGs are widely accepted and applied, I have been able to focus on application of CPGs, not confounding my findings with introduction of change.

3 Reflections on computerization of CPGs

As mentioned in the introduction, computerization may be conducted on the basis of various rationales: (1) as part of a multifaceted CPG implementation strategy (Dufour et al., 2006, Garg et al., 2005), (2) as part of configuration of computer systems within healthcare (Häyrinen et al., 2008, van Merode et al., 2004), or (3) as the foundation for developing and introducing business process management systems within healthcare (Mulyar et al., 2008b, van der Aalst and Pesic, 2006). It is still a topic for discussion whether the electronic record system should provide guidance and process support (Lenz and Reichert, 2007), or whether guidance should be designed as an independent application in relation to the electronic record system (ten Teije et al., 2008).

Computerization of CPGs may be executed in the most basic form as a knowledge management system or as more sophisticated computer interpretable guideline (CIG) systems or as full-fledged computer executable guideline (CEG) systems. The level of automation can be further graded as illustrated in Table 3:A.

- | |
|---|
| <ol style="list-style-type: none">1. <i>The computer offers no assistance: the human must take all decisions and actions</i>2. <i>The computer offers a complete set of decision/action alternatives</i>3. <i>The computer narrows the selection down to a few relevant alternatives</i>4. <i>The computer comes up with one suggestion</i>5. <i>The computer executes the suggestion if the human approves</i>6. <i>The computer allows the human a restricted time to veto before execution</i>7. <i>The computer executes and then necessarily informs the human</i>8. <i>The computer executes and only informs the human if asked</i>9. <i>The computer executes and informs the human if the computer, decides to do so</i>10. <i>The computer decides everything, acts autonomously, ignoring the human</i> |
|---|

Table 3:A Levels of automation based on Cummings (Cummings, 2004)

In relation to computerization of CPGs, only Cumming's six basic levels are really of relevance within hospitals, hence application of CPGs is fundamentally an issue of providing "*statements to assist practitioner decisions about appropriate health actions for specific clinical circumstances*" (Field and Lohr, 1990). When the clinician has made a decision on appropriate care, the ordering process can, however, be automated. In case of activities constituted of several sub-activities or corollary activities, ordering or execution of the corollary activities may be automated when the primary activity is ordered. For example, in case of ordering aminoglycoside⁹ for infections, corollary orders of blood levels of aminoglycoside could be automated (Bates et al., 2003).

Computerization of CPGs beyond basic presentation of CPG documents requires formalization of the CPGs. According to Aigner (Aigner et al., 2008) and Leong (Leong, 2007), CPG's can in principle be formalized by two different approaches:

- A model-centric approach or a

⁹ There is a CPG recommending that in case of aminoglycoside therapy beyond x days blood aminoglycoside levels should be monitored

- A document-centric approach

In the model-centric approach the first step is to let domain experts formulate a conceptual model based on the CPG. Thus the linkage between the model and the CPG is only indirect. The model-centric approach is the most commonly applied method for formalization of CPGs. Examples of this method are Protégé (Shankar et al., 2003, Noy et al., 2003) and Asbru (Shahar et al., 2004). In the document-centric approach, mark-up tools are used to systematically mark-up the CPG text in order to generate a semi-formal model of the marked text. An example of the document-centric approach is the GEM Cutter (Georg et al., 2005, Aigner et al., 2008).

Reflecting the scope of the CPG (as discussed in the previous chapter), focus in computerization of CPGs has been on provision of decision support (Greenes, 2007) or process-planning support (Isern and Moreno, 2008, Mulyar et al., 2008a). A large number of computer-based clinical decision support (CDS) systems have been developed over the last 40+ years. The main aim of CDS systems has been to optimize the problem-solving, decision-making and subsequent action sequence (Greenes, 2007). A core component in CDS is a decision model applied for organizing and analyzing contextual data and existing knowledge leading to a recommendation. CPGs may constitute the knowledge base in such a model. Although application of CDS systems has turned out to be promising in research cases, the propagation rate has been rather slow, and identified barriers have been hard to overcome (Denekamp, 2007, Trivedi et al., 2009). When CPGs are computerized as support for process planning, they have been presented in some kind of business process management tool, where focus is on planning of sequences of activities (van der Aalst and Pesic, 2006). Further, CPGs may be computerized as reminders and alerts (Bates et al., 2003) or as series of documentation templates (Bernstein and Andersen, 2008).

Several groups have developed formal languages to model computer-readable or computer-interpretable CPGs, such as Arden Syntax (Peleg et al., 2001, Denekamp et al., 2003), Asbru (Shahar et al., 2004), DeGeL (Shahar et al., 2004), EON (Tu et al., 2003), GASTON (de Clercq and Hasman, 2004), GELLO (Sordo et al., 2003), GESDOR (Wang et al., 2003), GEM (Georg et al., 2005), GLARE (Terenziani et al., 2004), GLIF (Peleg et al., 2000), GUIDE (Peleg et al., 2003), PRODIGY (Tu et al., 2003), PROforma (Sutton et al., 2006), Protégé (Shankar et al., 2003, Noy et al., 2003), SAGE (Tu et al., 2007) and SPREAD (Panzarasa et al., 2007). Some of these formalisms have merged over time, while others have emerged from splitting of formalisms into two new presentations (de Clercq et al., 2008). In the majority of the mentioned formalisms, focus is on the presentation of CPGs as workflows. Some, however, also provide the possibility of addressing reminders to specific actors (Quaglini et al., 2005). Besides these CPG-specific formalisms, several researchers within the area of business process management have been working with computerised business process support based on CPGs (van der Aalst et al., 2009, Mulyar et al., 2008b).

Relevance for this thesis: In the prototypes developed in relation to this thesis, a model-centric approach has been applied. The aim of the prototyping has not been to examine the transformation from textual CPG to computerized CPG, but to examine and refine the demands from clinical work practice and business strategy on computerized CPGs. The level of automation has been on level 3-4 in the ALS prototype and on level 4-5 in the chemotherapy prototype on the scale presented in Table 3:A.

4 Theoretical and methodological standing

The research questions have been examined within the field of oncology, and in relation to advanced life support (ALS). The two fields are well suited for the study of **how CPGs are applied in clinical work practice** and **what kind of demands clinical work practice and business strategy put on computerization of CPGs**, since CPGs are generally accepted and widely complied within the two areas. Within oncology CPGs and protocols have become a fundamental part of clinical work. The specialty could simply not function in the current form without CPGs and protocols, not just in relation to clinical research, but also in relation to ordinary clinical practice (Keating and Cambrosio, 2007). Within the area of advanced life support (ALS) The European Resuscitation council has undertaken the task of developing and publishing a CPG on ALS (European_Resuscitation_Council, 2005). This CPG is generally accepted within Danish healthcare, and the mandatory ALS training of clinicians in hospitals are designed to support the application of the guideline (Andersen, 2010). Therefore I find the two areas well suited for my research.

The theoretical and methodological principles that have guided my research are presented in the following.

Underlying theoretical foundation

When I started to work on this thesis, my basic assumption was that computerization of CPGs could promote application of CPGs in clinical work practice, and that the theoretical launch pad should be within health informatics.

Health informatics is, however, a relatively new area of research, thus it has not yet established a comprehensive set of theories and methods. Therefore, health informatics research is reliant on theories and methods from a wide number of adjacent research areas. Guided by literature studies I have found inspiration mainly within health sciences, information systems, business management, and learning and knowledge management. (Alavi, 2001, Stefanelli, 2004). Each of the research areas provide Health Informatics with theories and methods that are relevant in relation to computerization of CPGs:

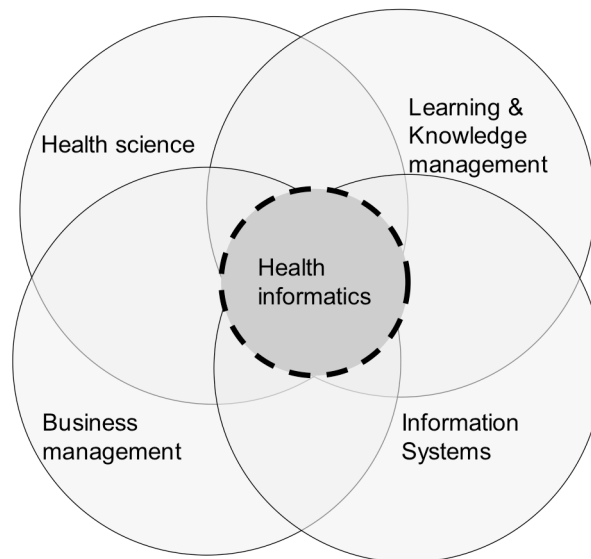


Figure 4-A Health informatics and the most important adjacent research areas, in relation to computerization of CPGs.

From the area of **Health sciences** comes theories on development of evidence-based medicine (EBM) (Sackett et al., 1998) as the foundation for high quality health care. A key dogma in EBM is that evidence from health science is the best basis for making decisions for individual patients as well as for health systems (Haynes, 2002). Therefore all clinical practice should rely on evidence that can be presented in systematically developed statements such as CPGs. From a health science perspective, computerization of CPGs can be regarded as a method for translating, transforming, and disseminating evidence into a format applicable in clinical practice (Davis, 2000, Kawamoto et al., 2005). Further theories on health professional's practice models (Johnson and Turley, 2006) and on the appropriate configuration of clinical documentation (Weed, 1968, Nygren et al., 1992) have a major impact on how computerization of CPGs should be designed.

From the area of **Information Systems** (IS) research a main contribution in relation to computerized CPGs come from the theories on computer-supported cooperative work (CSCW) (Schmidt and Simone, 1996, Bardram, 1997). The work practice within healthcare is characterized by being highly collaborative and exception filled (Pratt et al., 2004). Thus the field of CSCW studies of how people collaborate with each other and the role technology plays in this collaboration can bring major contributions to the design of computerization of CPGs. Computerized CPGs can be regarded as computer supported coordination of work, based on recommendation for standardised practice (Schmidt and Simone, 1996). A specific line of theories in information systems regards theories on Business Process Management (BPM) systems (Dumas et al., 2005). BPM provides the theoretical foundation for the design of computer-interpretable guideline (CIG) languages. Most of the CIG modelling languages are however still struggling with providing flexibility for handling of the frequently occurring exceptions in health care (Mulyar et al., 2008a). Further, the area of IS research provide theories on how to design information systems that are relevant to health informatics. In my research I have mainly found the theories of participatory design (PD) of IT systems (Kensing and Blomberg, 1998) relevant, hence the healthcare sector is dominated by professionals (Mintzberg, 1993) with firm beliefs in (and knowledge of) how health care should be practised. PD methods are suitable in the design of CPG computerization as they pay attention to the knowledge of the professionals in the design process.

From the area of **Business management** research, theories on change management within organisations (Grol, 2005c) have an impact on the design and introduction of computerized CPGs. The computerization of CPGs should be designed in a way that is consistent with the business strategy (Bødker et al., 2004) and the resistance to change in the organisation should be dealt with in the design of the implementation (Grol, 2005c). Further theories on total quality management in organisations (Powell, 1995, Grimshaw et al., 2006) have an impact when introducing CPGs, no matter whether they are computerized or not, as CPGs may be regarded as a presentation of professional knowledge and standards to guide the individual professional's behaviour and social interaction (Grol, 2005c, Bandura, 1997).

From a **learning and knowledge management** research perspective, theories on knowledge management (Alavi and Leidner, 1999) have a major impact as CPG can be regarded as a way of presenting the core knowledge within health care organisations. From a learning & knowledge management perspective, knowledge is a precondition for any specific behaviour of an individual practitioner (Bloom, 1956, Norman, 2002, Estabrooks et al., 2006). It is, however, well known that there are barriers between knowing and doing (Cochrane et al., 2007), thus attitudes and skills will also have to be addressed in the design and implementation of computerized CPGs as part of a multifaceted implementation strategy (Wensing and Grol, 2005b). Further theories on artificial intelligence (de Clercq et al., 2004, Stacey and McGregor, 2007) have an impact on computerization of CPGs, as computerized CPGs may be regarded as a kind of medical intelligence support, providing the foundation for decisions (Greenes, 2007). Computerization of a CPG may even be designed in a way where the clinical decision making is fully automated (Cummings, 2004).

As described above the assumption that computerization of CPGs may promote application of CPGs in clinical practice can find justification in several theoretical approaches. The heterogeneity of theories and perspectives is reflected in the comprehensive literature on CPG computerization (Greenes, 2007, ten Teije et al., 2008) (Dumas et al., 2005, Kaiser et al., 2004). The theories provide a framework of recommendations for the design and implementation of computerized CPGs, although there are no coherent theories of how IT supports the process of getting from medical research results via CPGs to changes of clinical practice.

Research methods

Computerization of CPGs can be part of various strategies for influencing clinical work practice addressing various organizational levels from the individual to the whole organization based on various theories as described in chapter 2 and 3. One could choose different theoretical approaches for research on computerization of CPG as sketched in the introduction to this chapter, as the questions imply a quest for obtaining new knowledge in a new realm of understanding. I have however chosen to apply a design science research approach; the reasons for this are explained in the following chapter.

I started out my research by doing interviews with project-managers on clinical content projects (Sundhedsfagligt Indhold – SFI) in all five Danish regions (Lyng and Kensing, 2008). The clinical content projects had emerged simultaneously in all the regions in relation to EPR development and implementation projects in the period 2005-2007. It however quickly became clear to me that although all the clinical content projects were designed as quality improvement projects, focus was only on clinical documentation, not on dissemination of new medical knowledge into clinical practice. .

I thus re-designed my research approach and decided to examine areas where I knew there was a high CPG impact in clinical practice, to come up with new insight in how guidance is applied in clinical work practice and how CPG application could be computer supported. I therefore set out to study the application of clinical guidance within oncology, concurrently I got involved in the design of a CPG-based tool for advanced life support (ALS).

Reasons for choosing an exploratory and design-oriented research approach

My research has been informed by an Information Systems (IS) approach, due to the scope of my research question. The core issue in this approach is the socio-technical interaction while introducing new technologies in organizational practice (Iivari, 2007). Therefore I have found it relevant to apply an IS approach. My application of the IS approach is founded on design science research, where ethnographical methods for collecting knowledge about the application domain are combined with building and evaluation of design artefacts that are based on but finally also expanding the knowledge base. This is well in line with the acknowledged design science research nestor Alan Hevner's ((Hevner, 2007) recommendations – see figure Figure 4-B. The other theoretical approaches listed in the introduction could have been beneficial if the scope of my research had been another.

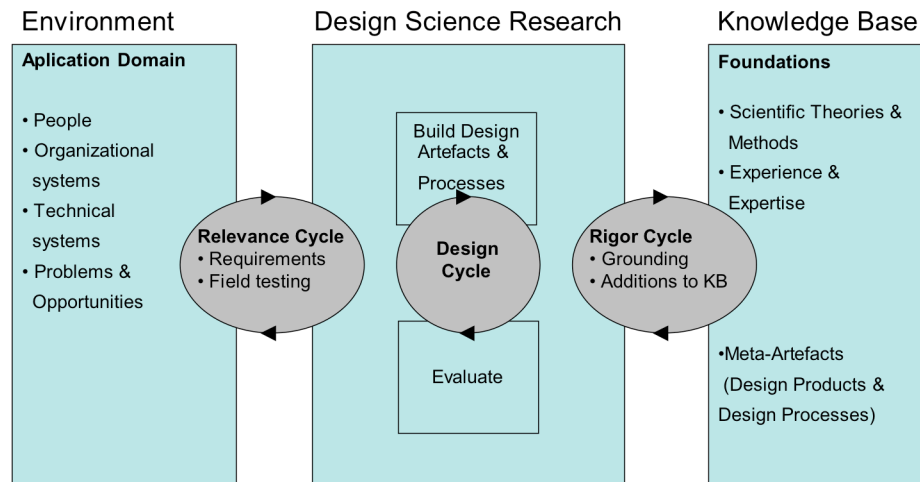


Figure 4-B Design Science research cycles from Hevner (Hevner, 2007)

In my research I have been working in all the three research cycles sketched by Hevner. In the selection of methods for examination of the application domain and designing and evaluating artefacts I have been following the research traditions within the IS areas of Computer Supported Cooperative Work (CSCW)(Pratt et al., 2004) and Participatory Design (PD)(Kensing and Blomberg, 1998). In the area of design I have been inspired by process technologies (Dumas et al., 2005) To develop a knowledge base I have done systematic literature reviews on my research topic.

Within healthcare quantitative methods in the form of randomized clinical trials (RCT) are regarded as a gold standard for research (Sackett et al., 1998) A quantitative approach would have been beneficial if the aim was to obtain knowledge on the prevalence and distribution of application of guidance in clinical practice. I have however deliberately deselected quantitative research methods, as it was already known that CPGs are scarcely applied in wide parts of clinical practice (Cabana et al., 1999, Quaglini, 2008). Thus quantitative methods were not expected to provide any substantial new insight into the questions of how guidance is applied in clinical work practice and what kind of demands clinical work practice and business strategy put on computerization of CPGs. On the contrary the “how” and “what” nature of my research questions entail that an explorative and qualitative approach should be taken (Strauss and Corbin, 1998, Pope and Mays, 2006). Qualitative methods are characterized by taking social, organizational, professional, and other contextual considerations into account (Kaplan, 2001). These issues are of major importance for the application of and compliance with CPGs (Kaplan, 2001). Further the research question implied that the research approach should take cognitive and social factors related to the design and use of technology into account (Patel and Currie, 2005).

The approach is well in line with the comprehension that the design and use of information systems is a social construct (Simonsen and Kensing, 1998). The application and the construction of information systems should therefore not be regarded as dichotomous but as inseparable. Acquiring knowledge on both application and design of information systems requires application of complementary though distinct research approaches (March and Smith, 1995). March and Smith argues that a two dimensional approach to IT research including both design science and behavioural science is fundamental to insure that IT research is both relevant and effective. The IT artefact is the core of IS research (Benbasat and Zmud, 2003), it is however intimately related to – and interacting with the tasks it should enable or support in

the application domain. Understanding the nature of these intimate relations in the artefact environment is achieved by behavioural science methods such as user-observations and interviews and constitutes the basis for my design research (Bødker et al., 2004).

The aim of the behavioural science approach is to develop theories that explain or predict organizational and human behaviour in relation to use of information systems in a domain. These theories can be used for addressing interactions among technology and actors that have to be managed in the design process if an information system are to achieve its purpose (Hevner et al., 2004). The design science approach is based on a pragmatic research paradigm where the fundamental aim is solving of real-world problems by creating innovative artefacts and artificial phenomena (March and Smith, 1995, Hevner et al., 2010, Avison and Elliot, 2005). The applicability and performance of the designed artefacts are however closely related to the environment in which they shall operate. Therefore there is a need for establishing a thorough understanding of the environment achieved through a behavioural science approach to ensure the design of artefacts that can work effectively and efficiently without any substantial undesired side effects. Further IT artefacts should be constructed on a knowledge base of existing scientific theories, methods and experiences, that can be achieved from systematic literature reviews (Hevner et al., 2010, Iivari, 2007).

The features and capabilities of the information system and the characteristics of the organisation, its work practice and its employees determine the socio-technical interaction. A successful interaction constitutes the basis for achieving the computerization aims. Therefore it was relevant to include both a behavioural science perspective a design science perspective and a systematic knowledge gathering in my study (Hevner et al., 2004, March and Smith, 1995).

The applied research methods

Although, in the following data collection, data analysis and construction design artefacts are described as separate themes, it has been carried out in an iterative process. Where observations have been made, preliminary results presented to users to initiate discussions resulting in further data on requirements that have been analyzed, applied and presented. To create an overview of my research methods however the issues have been separated in the following.

Data collection

In both the oncology and ALS case the first step was to examine how guidance actually is applied in practice. Subsequently prototypes were developed to test and further collect data on CPG computerization requirements.

In the oncology case I invited the three regional oncology departments to take part in the study, they all accepted the invitation and pointed out contact persons. An anthropologist and I each made 2 full days of observation in 3 oncology clinics, all in all 12 days of observation. During the observation a health professional: a registered nurse, junior house officer or senior consultant was shadowed for 2-6 hours in daytime of a normal working day. Concurrently unstructured ad-hoc interviews were made with health professionals on the use of CPGs. We kept a structured log on when guidance was requested by a health professional, and the format of the applied guidance – see an example of the logbook in Figure 4-C. All in all 66 incidents were registered where guidance was sought for - as this was not a quantitative survey identical incidents were only registered once. Beside the log we kept a diary of the observations, where anything of relevance to CPG application was noted. Further examples of applied guiding artefacts were sampled during observations. When the observation study was planned, extra observation days were scheduled as back-up, but due to the homogeneity of findings it was decided not to do further observations.

Format of the applied guidance	Clinical task	Function of the guideline	Actors
Pharmaceutical handbook	Ordering of medicine	Support for ordering of the right dosage of medicine	Physician
Pre-printed form - in standard format (one such form for every protocol)	Pre-medication (before chemotherapy)	Used as a standard order – the order is only given in this way. Serves also as a check list, where the nurse signs when the medication is administered to the patient	Nurse
1) External guideline found on the Internet, published by a group of specialists 2) Direct telephone contact to senior colleague in another specialty – specialises in the specific problem	Decision on whether to continue treatment of a rare side effect	1) Support for decision on continued pharmaceutical treatment 2) Check with specialist on correctness of interpretation of guideline	Senior consultant

Figure 4-C section of an observation log – my translation

The logs, diaries and interviews were transcribed immediately after the observations and a preliminary analysis of the findings was made. This was presented and discussed in staff meetings in the oncology clinics to initiate discussions and thereby prompt further data on requirements. Based on the gathered data a prototype was made for a specific clinical process: the order-preparation-administration of chemotherapy process (presented in paper A). The process has a CPG of its own, describing the recommended clinical organization of the activity. The process is included in all the chemotherapeutic treatment protocols applied in the clinics. The prototype was presented at workshops in two of the clinics to initiate further discussions on requirement for computerized CPGs, this triggered collection of additional data on requirements. Finally, another workshop was held at the design laboratory at the IT-University where further requirement data were collected.

The ALS case was initiated as a cooperation project with Danish Institute of Medical Simulation (DIMS) that wanted to develop CPG based process support for the cardiac teams doing advanced life support (ALS) within hospitals. A steering group was established for the project, including the manager of ALS training at DIMS, the head ALS teacher from DIMS, and a researcher from DIMS and me as the researcher from the IT University. A project group was also formed constituted of four health informatician thesis students that I supervised. Due to the logistic and ethic problems of doing observations in real cases, and the fact that two of the project group members were experienced cardiac team members it was decided only to do observations in the simulated, full scale, realistic training environment. This additionally entailed the benefit of videotaping of the observed sessions. Two full days of ALS training were observed. After the ALS training group interviews were made with the trainees. A questionnaire was given to all doctors within cardiology to quantify the doctors' experience

with performing ALS. The findings were analysed, and based on the results a set of proposals for a solution were developed. The proposals were presented in workshops at DIMS to initiate and refine the collection of additional requirement data. Subsequently a prototype was developed and tested in full-scale simulation. Based on analysis of the findings and feedback data this first prototype was further developed in cooperation with the ALS teachers from DIMS to a running prototype version, called CardioData (presented in paper B).

Data analysis and interpretation

The analysis was carried out in a non-linear process, going back and forth, although it could be divided into phases. In the first phase I read all the material thoroughly to familiarize my self with the data set. Secondly I re-read the material identifying key-topics that I marked in the textual data sets and registered in tables for the non-textual data sources. Then I started to ask questions like “when is guidance thought for?” “Who is seeking guidance?”, “What kind of guidance is requested” and “How is guidance obtained?”

Figure 4-D example of a mind-map used in the analysis of the observation study. This mind-map regards the guidance presented in standard forms, and is organized with the "non-interactive" information on the left side and the "interactive" (= where there is provided room for documentation) on the right side

Based on these analysis I started to develop interpretations, that finally led me to come up with theories on guidance for clinical practice. The process was reiterated several times, continuously refining the theories. Some of the emerged theories have been applied and tested in the development of the prototypes that have been presented to the clinicians for examination of applicability and as a mean to initiate and facilitate the discussion of requirements for computerized CPGs – that in turn lead to new data that was transcribed and

analyzed. Subsequently, the results have been validated by (a) critical examination and re-examination of analytical decisions, making changes when analysis of subsequent data sets challenged past coding decisions; (b) presenting and discussing the preliminary results of the analysis of present practice with clinicians to refine the categorization; and (c) validating final results by clinicians from the participating clinics.

Problem	Causes	Consequences	Ideas for solution
<i>Two-minute intervals for check-up on patient are not observed</i>	<p>4) <i>It is difficult to keep track of time in an urgent situation</i></p> <p>5) <i>The sense of time is lost and time is experienced differently by various team members</i></p> <p>6) <i>There is no master watch present</i></p>	<ul style="list-style-type: none"> • <i>The CPG algorithm is not observed</i> • <i>Inadequate quality of the ALS treatment</i> • <i>Non-application has an impact on patient survival and possible outcome (brain damage)</i> 	<ul style="list-style-type: none"> • <i>Digital "chess watch" in all hospital rooms, able of counting down in two-minute intervals</i> • <i>Ensuring a standing timer role</i> • <i>Integration between watch, computerized CPG solution and defibrillator</i>

Figure 4-E example of a diagnostic map for one problem. In the project several problems were identified. The numbers in the 'causes' column are sequential numbering of the causes identified in the project, i.e. several problems may be caused by the same causes.

In the ALS case Grounded theory was applied as in the oncology case, further diagnostic maps (Bødker et al., 2004) were used as method for analysis of data – see example in Figure 4-E. The diagnostic maps were discussed in the project steering group. Based on the consequences listed in the diagnostic maps the problems were prioritized according to severity in relation to patient outcome. This prioritization list was guiding the design of the artefact

Design and evaluation of prototypes

In both cases prototypes have been made with the purpose of testing theories developed on basis of analysis observation studies and interviews.

In the oncology case we had to design a task-network-model (de Clercq et al., 2008), of the process that should be supported by computerization of the CPG – illustrated in Figure 4-F. In this case it was a research aim to evaluate if it was possible to present the revealed requirements on signatures after performance of checks and the need for frequent reiterations of tasks in the process in a commercial workflow system. The model was presented to clinicians for validation before implementation in the workflow application.

In the oncology case the European Council's CPG on ALS already was presented as a workflow algorithm. The main aim of the first prototype was to test the design of a portable device with a user-interface presenting the general guidance from the CPG. Based on the first prototype it became clear that there was a need for prioritization of the user-interface in accordance with the problem areas revealed by the diagnostic maps.

Both prototypes were subsequently applied for gathering af further data on requirements for computerization of CPGs.

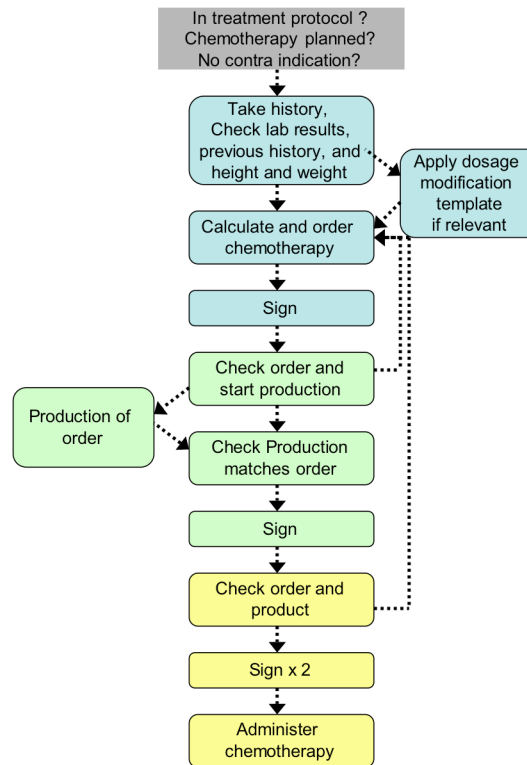


Figure 4-F The developed workflow algorithm for the oncology case, that was applied for the construction of the prototype. The different colours indicate various actors

Systematic review of relevant literature

Besides the qualitative research, a systematic search on 'computerization and clinical and guideline' have been carried out in PubMed¹⁰, EMBASE¹¹, AISeL¹² and ACM Portal¹³. The search period was limited to 1999 to 2010, as it was assumed that due to the development within the area, older research results would generally not be of much interest. Based on my reading of primary findings, I have also performed chain searching, including several significant sources prior to the original search period. Further I have made a systematic search on 'participatory design' in the same databases. All in all, I have collected more than 1.350 references relevant for the topic studied during my research period.

Reflections on quality criteria for the methodological approach

I have based most my reflection on the quality criteria that should be applied for design science research on Hevner, as he – and his research group – are notable and acknowledged proponents of design science (Hevner et al., 2004, Hevner, 2007, Hevner et al., 2010). The basic fundament of design science research is that knowledge and understanding of a design problem and its possible solutions are acquired through creation application and evaluation of innovative artefacts and artificial phenomena (March and Smith, 1995, Hevner et al., 2010, Avison and Elliot, 2005, Hevner et al., 2004). This research concept is therefore well suited for computerization of CPGs, hence it seems a reasonable assumption that a low penetrance of computerized CPGs could be due to design problems.

In order to evaluate my exploratory and design oriented research approach I have chosen to apply the design science guidelines proposed by Hevner et al (Hevner et al., 2004), as a benchmark. Hevner et al. have defined seven guidelines for good design research. In the following I have reflected on my methodological approach based on these guidelines – the original guidelines are in italics.

Guideline 1: Design as an artefact

Design-Science research must produce a viable artifact in the form of a construct, a model, a method, or an instantiation.

In both the empirical cases prototypes were designed to test theories and gather additional requirement data. Further I have shown that PD is a beneficial method for the design of computerized CPGs (Paper F)

Guideline 2: Problem relevance

The objective of design-science research is to develop technology-based solutions to important and relevant business problems.

I have made a systematic review of the literature and found that clinical non-application of CPGs is realised as a major problem, implying delayed or non- introduction of new medical evidence in clinical practice (Grol, 2005b). If the basic assumption that CPG computerization will improve CPG application is correct, then computerization of CPGs will help overcoming some of the problems with non-application of CPGs. The comprehensive

¹⁰ PubMed is a service of the American National Library of Medicine that provides access to over 17 million citations from MEDLINE and additional life sciences journals.

¹¹ Embase is a comprehensive database which holds over 20 million indexed records from more than 7,000 active, peer-reviewed journals.

¹² AIS e-Library is Created and maintained by the International Association for Information Systems AISeL holds conference papers for AIS-sponsored and affiliated conferences, content from AIS SIGs and Chapters and the most prominent academic journals.

¹³ The ACM Portal is published by the Association for Computing Machinery, it holds 54000 on-line articles from 30 journals and 900 proceedings.

application of forms and other guiding artefacts that had been transformed from CPGs according to a standard operating procedure in the oncology clinics could indicate that the assumption is correct.

Guideline 3: Design evaluation

The utility, quality, and efficacy of a design artifact must be rigorously demonstrated via well-executed evaluation methods.

In the oncology case the prototype- a desktop presentation - was demonstrated in workshops with physicians and nurses. The prototype served as a tool to initiate discussions on requirements. In the ALS case the prototype was tested in full-scale simulation, measuring relevant clinical process indicators.

In both cases the applied evaluation method matched the aim of the evaluation; the oncology evaluation focussed on collection of requirement data, while in later iterations in the ALS case focus was moved towards testing of application in practice.

Guideline 4: Research contributions

Effective design-science research must provide clear and verifiable contributions in the areas of the design artifact, design foundations, and/or design methodologies.

In the oncology case the evaluation of the prototype made it clear that integration of computerized CPGs to relevant existing sources of patient information, that constitutes the conditions for decision-making are mandatory. In the ALS case a profound interplay of application and hardware was found to be critical.

Further both cases elucidated the close relation between recommendations and documentation of execution that have to be supported when designing CPG computerizations. Further it was found that CPG recommendation should be presented when relevant in an activity specific way at the point of care.

Guideline 5: Research rigor

Design science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact.

In both cases the collection of requirements data is based on source triangulation applying various widely accepted methods. The construction of the artefacts were then based upon formal models of the CPG-based workflow. The workflow models have been verified by clinicians in the observation sites. In the oncology case the artefact has been tested in desktop tests with clinicians. In the ALS case there has been full scale testing in a simulated environment, applying realistic outcome indicators.

Evaluation and evaluation criteria for CPG computerization however could be refined as part of further research, focussing on what should be evaluated and how evaluation should be carried out.

Guideline 6: Design as a search process

The search for an effective artifact requires utilizing available means to reach desired ends while satisfying laws in the problem environment.

In both cases a comprehensive literature search have been made. Further a search for available means were made based on the emerged requirement specification. This lead to the use of a commercial workflow engine in the oncology case and an ultra-light PC in the ALS case. None of these artifacts fulfilled all the established requirements, but were the available means. The rules and regulations of the healthcare area were included as profound premises in the design process.

Guideline 7: Communication of research

Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences.

Results from both cases have been presented in the observation sites, at conferences on health informatics and in papers.

Strengths and limitation of my methodological approach

The aim of my research was not to establish any quantitative evaluation of the application or non-application of CPGs, but to establish increased knowledge about how guidance is actually applied in clinical practice and the demands clinical work practice and business strategy put on computerization of CPGs. Thereby providing a fundament of requirements and requirements specification methods to be applied when computerizing CPGs.

The challenge of where and how to do research

First I had to make decisions on where and how to do my research (Friedman and Wyatt, 2005) As sketched in chapter 2 there are various motives for introduction of CPGs and aims to be achieved by the introduction. I have decided not to let any of these perspectives constitute the basis for my research. Instead my perspective and starting point has been the existence and actual application of guidance in clinical practice. By doing my empirical research within oncology and ALS, where protocols and guidelines are widely accepted concepts, I have overcome most – but not all - of the problems related to the obscurity of the CPG concept and the difficulties with implementation of CPGs (as discussed in chapter 2).

I decided to apply a design science research approach because clinical practice fundamentally is a human endeavour, where there is a need for establishing new knowledge by bridging disciplines to enable clinicians to benefit from technologic advances. Further, I decided to go for a qualitative research approach, as qualitative methods are suited for finding answers to questions of the what and how and why kind, by taking into account social, organizational, professional, and other contextual considerations of major importance for the application of CPGs (Kaplan, 2001, Pope and Mays, 2006). A shortcoming of ethnographic and behavioural qualitative research however is that it regularly is met with demands on justification the scientific results (Strauss and Corbin, 1998, Pope and Mays, 2006). The critique of qualitative research often touches upon the issue of reaching generalizability, reliability and validity of research results. These concepts have achieved status as the holy trinity in research, although the objectivity and universal truth of the concepts are up for discussion in a postmodernistic perspective (Kvale, 2005). I have addressed the issue of generalizability by source triangulation (Patton, 1999) - applying several methods (observations, interviews, document analysis) to achieve data. The problems of achieving reliability and validity I have addressed by ongoing presentations and discussions of my results with clinicians. But of course it can be argued that I have not touched upon every stone and I must agree that there is a need for further research to increase the reliability and validity of my findings.

The choices I have made on where and how to do my research may imply some limitations in the generalizability of my results. It can be argued that the high CPG acceptance within oncology and ALS are due to specific – although unknown – organizational or human factors in the two areas that also affects the work practice and business strategy. I have not been able to find such a reverse causal relation but I cannot exclude that it exists. Therefore there is a need for further research addressing other clinical specialties.

The major challenges of the applied methods

Objectivity and professional distance to the area of research are key issues in qualitative research (Friedman and Wyatt, 2005). My background as a physician, MBM, MI with many years of job experience in departments where quality improvement, post-graduate training and medical informatics have been high on the agenda can be seen both as a strength and a limitation in relation to objectivity and professional distance. On the one hand my background has helped me to see and understand details that otherwise not would²⁴

have been registered. On the other hand it might also have blinded me, not registering things that I find trivial. In the observation studies it thus have been helpful to do the observations together with persons with another educational and experiential background.

Some would argue that the empirical work has not been extensive. This is right if the aim was to make ethnographic studies. This was however not the aim, the aim was to establish knowledge about current application of guidance in clinical practice with consequences for future computerization of CPGs. In both cases it rapidly became clear that it was the same issues that were registered repetetively, indicating that this were the most prominent issues.

I have applied several methods for data collection each of them has its strengths and limitations regarding quality and completeness of data. The limitations can for a major part be overcome by source triangulation as mentioned above. This will however not guarantee that all data of relevance are collected.

Applying a grounded theory approach for the analysis of data implied that the field of research was met without any predefined theoretical explanations to be confirmed or rejected (Strauss and Corbin, 1998). Although my research is based on the basic assumption that computerization of CPGs can enhance application of CPGs if the computerization is properly designed. The aim of my research has only been to come up with requirements for proper design. In my analysis and interpretation of data there was both a possibility and a risk of taking certain perspectives into account and letting others out based on my (un-) conscious pre-understanding (Bowker and Star, 2000). I have tried to overcome this by thorough analysis and repeated analysis and by letting clinicians validate my results.

The theories developed applying a Grounded theory approach can be related to the existing theories that was briefly introduced in the introduction of this chapter. It became however quickly clear that while those theories were beneficial for analysis of existing approaches and artefacts, they proved not to be helpful for designing them. In the design process I found it essential to take a starting part in the challenges of the work practice and the business strategy, although this inevitably will include aspects of the presented theories.

The use of prototypes was on one hand an efficient method to initiate discussions and thereby for collection of additional data, on the other hand it may have limited the imagination of the clinicians focussing their conceptions in a specific direction. This I have tried to avoid by presenting the prototypes relatively late in the projects. In this way the prototypes have helped me validate some theories and reject others.

Outline of strength and limitations

The applied research methods the empirical field and my personal background put some limitations to my findings. The generalizability outside clinics where CPGs are widely accepted and complied with can be questioned. The value of doing empirical studies in clinics where CPGs are not generally applied and complied with is however doubtful, as there would be several confounding factors implying the findings. The strength of the findings could have been improved by applying method triangulation (Patton, 1999), this was however not possible due to the and resource limitations. In the data analysis and interpretation I have tried to be as objective as possible, multi-observer coding and interpretation would however have been beneficial, but this was however not a practical option. Most of these imitations are inherent in the applied methods, although I have tried to address them in the application of the methods.

In spite of these limitations I have been able to come up with new knowledge on how guidance is applied in clinical practice and the demands that clinical work practice and business strategy put on computerization of clinical practice guidelines. These demands I have thoroughly tested using various methods to improve the generalizability, reliability and validity of my findings. The focus in my research have always been on the on the relevance of findings (Hevner, 2007) for clinical practice. This I see as strength hence it can facilitate the application of my findings in clinical practice although other might find it un-academic.

5 Contributions

This thesis is based on the following papers:

- Paper A: Lyng, K. M., Hildebrandt, T. and Mikkamala, R. R. (2009). From Paper Based Clinical Practice Guidelines to Declarative Workflow Management .In *Lecture Notes in Business Information Processing* vol 17 p 336-347, 2009.
- Paper B: Pedersen, B. S., Jeberg, K. A., Koerner, C., Balslev, C., Andersen, P. O., Jensen, M. K. and Lyng, K. M. (2009). IT for Advanced Life support in Hospitals. In *Studies in Health Technology and Informatics* vol. 143 on *Advances in Information Technology and Communication in Health* p 429-34, 2009.
- Paper C: Lyng, K. M. Translating clinical practice guidelines into practical clinical guidance artefacts – implications for computerizations of guidelines. In *SHI 2009 proceedings* p 44-49, 2009.
- Paper D: Lyng, K. M. (2010). From Clinical Practice Guidelines, to Clinical Guidance in Practice – Implications for Design of Computerized Guidance. In *Studies in Health Technology and Informatics* vol. 157 on *Information Technology in Health Care: Socio-Technical Approaches 2010*. p 169-174
- Paper E: Lyng, K. M. (2010?). Guiding artifacts presenting medical knowledge at the point of care – implications for computerization. Submitted to the International Journal of Medical Informatics, March 2010 – 24 pages
- Paper F: Lyng, K. M. and Pedersen, B. S. (2010?) Participatory Design for computerization of clinical practice guidelines. Submitted to Journal of Biomedical Informatics, October 2010 – 23 pages

In the following chapter, the abstracts of the included papers are presented, followed by a short presentation of the major contributions to the research questions:

RQ1: How is guidance applied in clinical work practice?

RQ2: What kind of demands do clinical work practice and business strategy put on computerization of clinical practice guidelines?

Chapter 0 contains a condensed summary of the assembled contributions from all the papers.

Paper A

Title: From Paper Based Clinical Practice Guidelines to Declarative Workflow Management

Abstract: We present a field study of oncology workflow, involving doctors, nurses and pharmacists at Danish hospitals and discuss the obstacles, enablers and challenges for the use of computer based clinical practice guidelines. Related to the CIGDec approach of Pesic and van der Aalst we then describe how a sub workflow can be described in a declarative workflow management system: the Resultmaker Online Consultant (ROC). The example demonstrates that declarative primitives allow to naturally extending the paper-

based flowchart to an executable model without introducing a complex cyclic control flow graph.

Contributions to RQ1: We found that the existing CPG portal was rarely used, except by novices. Cultural factors like extensive oral communication and no managerial pressure on use of CPGs implied low application. Further clinicians feeling of competence reflected in statements like: *“I have been here for a hundred years, so I know what to do and I know the procedures”* implied that guidance was not sought for. Neither did we observe any extensive use of the printed protocols that could be found in binders in all the offices in the outpatient clinics.

Instead we found several standardised paper-based forms such as treatment overview form and process flowcharts guiding the clinical work. Guidance profoundly embedded in the work practice in form of documentation templates, standard order sets in CPOE or decision algorithms on pre-printed forms were found to be frequently applied.

The activity of ordering, preparing and administration of chemotherapy was scrutinized. We found that guidance of the activity was minimal focusing on securing safety. The flowchart that supported the activity was found to serve several functions: it guided the workflow, it served as a documentation template, and thus also as a legal document. As the work was distributed among several actors in various places, the flowchart supported coordination of the work. The flowchart also functioned as a physical token indicating the responsible actor. The physicality of the flowchart however implied that it was only the actor currently possessing the form who had a detailed overview of the state of the process. The last actors in the workflow used much time tracing the paper form to obtain a status of the process.

Contributions to RQ2: The clinicians spontaneously expressed an interest in having computerized guidance, but it was a prerequisite that it at least could fulfil the functionality of the current guiding artefacts and that application did not require interruptions in clinical work. Forms and order sets were found to be comprehensively applied as a method for translating of medical knowledge into practice, thereby serving as guiding artefacts.

We found that a relatively simple procedure such as ordering, preparing and administration of chemotherapy had an extension in both time and location and included several actors with different roles. This implied demands on access to the same instantiated CPG in several places, support for handover of responsibility between actors and transparency of the status of the workflow.

A key issue in the developed prototype was to provide business process management and to provide support for business strategic demands on safety and transparency of work. This was done by establishing support for checkpoints, where a check was verified by application of a digital signature and failure at a check implied reiteration of previous task(s). Further the prototype was established as a web-based solution with a simple role model managing access rights.

The prototype was designed to support the workflow (process support), but did not provide any support for individual dosage calculation (decision support). Support of dosage calculation would require integration to relevant sources of patient information.

Paper B

Title: IT for Advanced Life Support in Hospitals.

Abstract: In this study we have analyzed how IT support can be established for the treatment and documentation of advanced life support (ALS) in a hospital. In close collaboration with clinical researchers, a running prototype of an IT solution to support the clinical decisions in ALS was developed and tried out in a full-scale simulation environment. We called this IT solution the CardioData Prototype.

Contributions to RQ1: We found a multifaceted learning & knowledge management approach for introduction of a new CPG on ALS. The approach included a “multi-²⁷

professional cardiac arrest team training” program and a pocket form presenting the recommended activity algorithm. Further computerization of the CPG was sought for as yet another facet in the multifaceted approach.

Contributions to RQ2: Cardiac arrest is characterised by being a hyper acute event, where a team of random actors are put together to fill out specific roles. The individual team members may however not have had much hands-on experience with ALS. This put high demands on simple and precise guidance that can be used by the individual team member under stressful working conditions – independent of experience - and as a basis for cooperation.

In this case it was found that there was no need for individual adaptations of the guideline recommendations based on existing patient information. An exception though was in the case of cardiac arrest in children where the recommendations are weight dependent. In the design process of the prototype it was thus decided that the clinician had to enter weight data for children. It was however found that there was a need for close integration between guidance and documentation as some guidance was dependent on data of previous actions in the LS process.

Further, it was found that due to the possible ubiquitous occurrence and strong demands on teamwork in relation to ALS there were profound demands on the physical design of the guiding artefact. It should on the one hand be easy portable and on the other have a display that easily could be overviewed by all the team members. Due to the stressful urgent working situation and the ad-hoc team the user interface had to be simple.

The business strategic aim on this prototype was to ensure effective compliance with the recommendations and support cooperation in the ALS team. Further it was a business strategic aim to ensure documentation on the fly.

Paper C

Title: Translating clinical practice guidelines into practical clinical guidance artefacts – implications for computerizations of guidelines.

Abstract: Much effort has been put into developing clinical practice guidelines (CPG's), but still the clinical adherence and thus the clinical effect of CPG's are limited. During the last decade computerization of CPG's as a method for propagation and dissemination of CPG's have been tried out. Most of the computerization of CPG's has been conducted as workflows. In this paper an observation study of the use of guiding artefacts in clinical practice in three oncology clinics is presented. It was observed that although the application of voluminous traditional narrative CPG's was scarce, a broad variety of guiding artefacts were applied in daily clinical practice. The majority of the guiding artefacts applied was related to specific tasks or closely integrated to documentation in relation to the task. Thus it is proposed that computerization of CPG's should not only focus on workflows, but be conceived as an integrated part of a coherent vision for introduction of IT in clinical work.

Contributions to RQ1: Comprehensive narrative CPGs were found to be infrequently applied in clinical practice. Although there are computers in all offices, examination and treatment rooms, junior doctors complained that they did not have computer access and therefore no direct CPG access in patient rooms in the wards and in the admission area. Further it was expressed as a problem that there was very limited time for consultation of guidance in the daily work practice.

A comprehensive number of paper forms including documentation templates and calculation schemes were however found to guide the clinical work practice. These guiding artefacts were found to provide various types of guidance: on what to do, on when to do it and on how to do it, as well as guidance on calculations and classifications. The guiding artefacts were found to integrate guidance and room for documentation. Further the artefacts were found to support cooperation between actors.

The guiding artefacts were produced locally as it was a tradition that the individual clinic was responsible for printing of forms. Those responsible for the creation of forms₂₈

acknowledged that it could be beneficial to make the forms in a closer cooperation with the other oncology clinics in the region, as most of the applied protocols were identical.

Contributions to RQ2: The primary demands were that guidance should be easy and speedy to apply, including access to relevant patient information and an overview of the patient's pathway. Further there was a request for process support including automation of ordering and automated reminders. The possibility of just having to document deviations from a plan was put forward. It was demanded that guidance should be presented in a flexible manner, where it would be easy to comply with or turn down any recommendation. Clinicians requested that computerized clinical processes should be flexible – providing the possibility of adding or removing activities. Further, it was a request that guidance should be provided in a way that supported clinician and patient mobility. Finally it was a demand that the user interface should be intuitive not requiring any profound education and that redundancy of information should be avoided.

It was a clear demand from the clinicians that development of computerized CPGs have to be closely integrated to development of other clinical IT applications. The clinicians did not profoundly distinguish between guidance and other clinical IT systems, but wanted to have an integrated clinical IT system where it would be possible concurrently to obtain relevant medical knowledge and contextual information for clinical decision-making and planning. The clinicians predicted that ease of access to all types of relevant knowledge and information for all actors was to be the decisive element in computerized guidance in clinical practice.

Paper D

Title: *From Clinical Practice Guidelines, to Clinical Guidance in Practice – Implications for Design of Computerized Guidance.*

Abstract. This paper presents a case study of clinical guidance within oncology clinics. Close to all patients treated within the observed clinics were treated according to a research or standard treatment protocol. The protocol artefacts were however rarely applied in clinical practice instead we found an extensive application of what we have named second order guiding artefacts. The deployed protocols underwent a local adaptation and transformation process when initiated. The protocols were adapted to match the local resources and transformed into several activity specific second order guiding artefacts. The transformation from protocols was executed according to a standard operating procedure. Each activity type had a standardized template ensuring uniformity across second order guiding artefacts within a clinic. The guiding artefacts were multi-functional and a wide variety of standardized graphical attributes were applied to support effortless appliance. The implications for computerization of clinical practice guidelines are discussed.

Contributions to RQ1: It was clear that the wide number of currently applied forms and standard order sets serve as the primary source of guidance in clinical practice.

When a managerial decision on application of a protocol was made, the protocol was adapted to match the local work practice and resources and subsequently the protocol was transformed into a series of activity specific second order guiding artefacts. In the transformation process the protocol and eventual elements from other CPGs were chopped into activity specific bits that subsequently were reassembled in activity specific second order guiding artefacts. Numerous physical features were applied to secure a unique presentation and to promote ease of application in clinical work practice.

Contributions to RQ2: The findings imply that there is a need for local adaptation of CPGs and protocols developed outside the organization, to ensure a match to the local clinical work practices and resources.

Further, there is a request for transformation of CPGs and protocols into activity specific guidance including physical features to support ease of application.

The local adaptation and transformation process were found to be a prominent part of the translation of medical knowledge into practice.

Paper E

Title: *Guiding artefacts presenting medical knowledge at the point of care – implications for computerization.*

Abstract

Objective: Much effort has been put into the development and publication of clinical practice guidelines (CPGs) to promote effectiveness, efficiency and safety within healthcare. The application of CPGs in clinical practice are however deficient. Computerization of CPGs has been proposed as a method to promote application. Computerization of CPGs has until now focused on formalization of CPGs and have only had a limited impact in practice. This study sets out to examine application of CPGs in clinical practice, focusing on implications for computerization.

Methods: An observation study on the application of guidelines in clinical practice within oncology was made. The observation study was supplemented with interviews and collection of guiding artefacts. Further workshops were held with clinicians defining requirements for guidance in daily work practice.

Results: Textual CPGs were rarely used. However, we found comprehensive application of numerous forms and predefined order sets that we conceptualize as second order guiding artefacts. Second order guiding artefacts have several characteristics: they are locally transformed from textual CPGs according to a standard operating procedure, they are activity specific, present at the point of care, embedded in the work practice and support coordination in clinical practice

Conclusion: The functionality and features of the applied second order guiding artefacts should be taken into account when computerizing CPGs. This implies that local adaptations, activity specific support, presence at the point of care integration into work practice and coordination support, are dealt with in the design of computerized CPGs.

Contributions to RQ1: Based on a thorough analysis of the current application of guidance in clinical work practice the concept of second order guiding artefacts is emerged. Second order guiding artefacts are characterized by being locally transformed activity specific, profoundly embedded in the work practice and support coordination among clinicians in the daily work practice.

By being activity specific the second order guiding artefacts only provided situational guidance and thus were easy to apply by busy clinicians. Activities could be overriding like planning of a whole patient pathway or restricted like monitoring of the patient while chemotherapy is administered. Several second order guiding artefacts may be applied concurrently for various activities.

Clinical decisions are made based on relevant knowledge and contextual information, therefore it was important for clinicians to have easy access to such information. Many of the applied second order guiding artefacts had room for presentation of contextual knowledge in the form of existing patient data and for documentation of occurring data. Transcription of data from one source to second order guiding artefacts was not comprehensively applied as it was considered to imply a risk of transcription errors as well as double work. The documentation templates were however comprehensively applied, as they made it possible to do the documentation at the point of care. Although documenting in forms entailed a risk of missing the information in subsequent encounters.

The second order guiding artefacts were presented either as paper forms or as standard order sets integrated in CPOE. The paper forms are portable and the standard order sets are profoundly integrated in the ordering process, thus second order guiding artefacts were always present at the point of care.

Guidance and coordination of work were found to be closely intermingled. Complying with guidance imply standardization of work processes.

The clinicians perceived guidance as a resource for planning rather than a determining factor when planning for a specific patient. The patient plans were frequently altered either due to patient related or organizational issues.

Contributions to RQ2: The concept of second order guiding artefacts is exhaustively analyzed focusing on the comprehensive implications for computerization if the functionality is to be substituted by computerized CPGs.

Clinicians demanded that computerized guidance should at least match the functionality of the current second order guiding artefacts, preferably with some extensions. This entails that guidance should be present at the point of care, activity specific and provided simultaneously with access to relevant existing information and room for documentation. Further computerized guidance should be developed to fit local work practice and resources and to support cooperation among actors.

Clinicians in my study requested to have automated ordering when a standard patient pathway is initiated as well as automated reminders when specific tasks are due.

Paper F

Title: *Participatory design for computerization of clinical practice guidelines*

Abstract

Clinical practice guidelines (CPGs) are computerized for various reasons, applying many kinds of formalisms. Computerized CPGs have, however, not yet achieved any general application in clinical work practice. We argue that one reason for this is due to the design methods applied for computerization of CPGs. The commonly applied methods for computerization of CPGs do not include requirements from clinical work practice and business strategy. Participatory design (PD) where the users are actively involved in the design process does include these aspects. A review of the literature on PD focusing on issues of relevance for CPG computerization is presented. Additionally, the application of PD for computerization of CPGs is illustrated by two cases. We conclude that PD is a beneficial approach when designing computerized CPGs.

Contributions to RQ1: The focus area in this paper is not on current applications of CPGs, but on methods for disclosing requirements in the design process.

Contributions to RQ2: This paper provides a review of PD approaches relevant for computerization of CPGs. The paper focus on three PD approach issues of major relevance for design of CPG computerization: 1) philosophy and politics behind the design approach, 2) tools and techniques applied in the design process 3) the need for establishment of a realm for understanding. PD can be regarded as an epistemological approach to the design process or as a way to provide users with direct influence on the process. In any case a PD approach implies that a user perspective is incorporated in the establishment of requirements. Users are to be understood in a broad sense including end-users as well as managers from the field of application. Therefore a PD approach can help provide a broad perspective when establishing the requirements that clinical work practice and business strategy put on computerization of CPGs. The PD toolbox provides a wide number of tools and techniques that can support the interaction between professional IT-designers and users in the process of establishing requirements on CPG computerization. The aim of these tools and techniques is to establish a shared realm for understanding among those involved in the design process, leading to an efficient gathering of requirements and design proposals.

Based on the literature review and the two case studies that have been presented earlier (Paper A, B and E) it is concluded that a PD approach would be beneficial for the design of computerized CPGs.

6 Concluding remarks

This chapter summarizes the main results and contributions of my research, addresses some challenges and outlines some directions for future work.

Main results and contributions

The contributions of this thesis consist of two main components:

- An analysis of how guidance is applied in clinical practice, within areas where CPG compliance is known to be high. The focus has been on emergence of general clinical work practice demands on guidance
- An analysis of guidance demands from clinical work practice and business strategy, with focus on implications for design of computerized CPGs.

Demands on computerization of CPGs can be divided into three main areas of origin: demands from the clinical work practice, demands from the business strategy and intrinsic demands from the CPGs. So far, there has only been limited focus on the two first mentioned areas of origin. In my research, I found that the comprehensive work practice and business strategy demands should have a much greater influence on computerization of CPGs in order for the computerizations to have any impact in daily practice.

I have chosen to make my empirical research within clinical work practice areas where CPG application is generally accepted, thus allowing me to focus on how guidance is applied and not confounding my examination with already well-known barriers to CPG application.

Application of guidance in clinical work practice

In the two clinical areas that I have examined the application of CPG differs significantly. The differences can be related to major differences in work practice. In ALS the clinical work may occur ubiquitously at any time, is carried out by an ad hoc team and have to be performed urgently under very stressful conditions, as it actually is a matter of life and death. While in the oncology clinics most of the clinical work is planned – although rescheduling is frequent, carried out at permanent work places or patient rooms, the clinicians cooperate in stable teams following the course of a patient's disease. These differences in work practice imply some differences in the application of guidance, although most of the differences mainly regard application of the guiding artefacts for other purposes than pure guidance.

In both cases I found that the existing CPG intranet portals were rarely applied in clinical practice (Paper A and E). In the ALS situations there is no time for checking anything on a computer in the oncology clinics the reasons may be more complex, although the time issue also here is prominent (Paper A and E). Nor are the printed treatment protocols extensively applied in the oncology clinics, although the majority of patients were treated according to a protocol. The clinicians expressed that they perceived application of the CPG portal and printed protocols as inconvenient since application required interruption of time-constrained work. Instead, I found a comprehensive application of pre-printed paper forms and standard order sets. I propose to refer to these forms and order sets as second order guiding artefacts as they have been transformed from textual CPGs or protocols (primary guiding artefacts) into another format (Paper C and E).

Second order guiding artefacts were found to have several characteristics: Within oncology they are locally adapted and transformed from textual CPGs according to a standard operating procedure, although it was acknowledged that a broader cooperation on the production of second order guiding artefacts would be possible (Paper D and E). In ALS

a laminated nationally developed one-page pocket manual is applied. Further the applied guidance is characterized by being activity specific, present at the point of care, embedded in the work practice and help support coordination in clinical practice (Paper E).

Activity specific guidance implies that it is only guidance relevant for a specific activity or task that is provided, not the whole guideline on how to handle a specific disease. This entails that the guidance is very precise and can be kept within a single page, which in turn supports a quick overview of the relevant guidance (Paper B, C and E).

Clinicians avoid interruptions in their work practice, thus the applied guidance should be **present at the point of care**. This implies that guidance is provided in a format that is adjusted to the work context (Paper A and B). It may imply portability (Paper B), but it can also be achieved by a solution that is accessible from computers placed at the point of care (Paper A).

The clinicians did not perceive the second order guiding artefacts as CPGs, as they were profoundly **embedded in work practice**, although the clinicians recognized that the second order guiding artefacts provided guidance. The second order guiding artefacts were however rather perceived as essential work tools (Paper A, D and E).

Guidance should be **flexible** and provided in a way that that can serve as a source for planning and decision-making, but not be an impediment in the work practice. The guidance should be provided with easy access to existing relevant (often conditional) patient information and room for structured (recommended) documentation support application of the artefacts in clinical practice (Paper A, B and E).

Standardisation of work practice through CPGs in itself support **coordination of work**. Making the CPG based work process transparent for all actors can help improve coordination (Paper A, B and E).

It was a basic characteristic of all the demands from clinical practice that clinical guidance should be provided in a way that supports efficient and smooth clinical work practices.

Further, I found that clinicians perceived guidance as a resource for planning of health activities, rather than as a determining factor. Plans were frequently altered either due to patient-related or organizational issues.

The currently widely applied paper-based second order guiding artefacts have, however, some major drawbacks: Paper forms are not easily integrated into any sources of information, and updating due to occurrence of new knowledge is inconvenient. Further, in a clinical work practice where computers are introduced as the main source of clinical information, it is inconvenient that the patient data that constitute conditional data for decision making and planning is separated from the clinical guidance and finally the documentation related to an activity.

It was indeed a clearly stated requirement from the clinicians in my research that computerized CPGs should be an integral part of IT within clinical work practice. It was expectancy that it should be introduced as part of the configuration of clinical IT systems (paper E).

Clinical work practice and business strategy impact on computerization of CPGs

Application of several examination methods helped disclose exhaustive demands from clinical work practice as well as business strategy on computerization of CPGs (Paper F).

The above mentioned clinical work practice demands on guidance combined with issues, such as ubiquity of workplace, required cooperation among clinicians, urgency of tasks, and demands on access to existing data, should all have a major impact on the design of computerized CPGs. Therefore, scrutinizing work practice is mandatory before designing computerized CPGs (Paper F).

Furthermore, business strategic aims have a major impact. Firstly, the overall strategic decisions as to the introduction approach for computerized CPGs have to be

made. Secondly, strategic aims and prioritization on quality improvement targets have to be made. Thirdly, strategic aims on the level of automation to be achieved have to be dealt with. Finally, a whole bulk of various strategic aims to be pursued in connection with the computerization of CPGs have to be addressed.

A decision on the implementation of any new CPG should imply a strategic decision as to the introduction approach: Should it be a health science approach focusing on translating new medical knowledge into practice? Should it be a CSCW approach applying the CPG as the basis for design of computer supported coordination of work? Should it be a business process management approach applying the CPG as a process description? Should it be a knowledge management approach applying the CPG as a source of business knowledge? Or should it be yet another approach? The decision will have a major impact on the design and introduction of computerized CPGs (As sketched in the introduction in chapter 4).

Prioritization of quality improvement aims such as safety; effectiveness, patient-centeredness, timeliness, efficiency and equitability to be pursued by computerization of CPGs were also found to have a major impact on the design of computerized CPGs. It has an impact both on functionality and physical features (Paper A and B).

Business strategic decisions as to the level of automation to pursue by computerization of CPGs have a major impact on the design, not only of the computerized CPG but also on the rest of the clinical IT system that will have to provide conditional information for decision- making and execution of activities in a standardized format (Paper A and B).

Finally, other business strategic aims, such as focus on transparency of processes or support for checkpoints and signatures, will have a major impact on the design of computerized CPGs (Paper A).

Moving from paper-based guiding artefacts to computerized CPGs will require new standard operating procedures to be established for the introduction and updating of CPGs in the clinical work practice (Paper D).

Scrutinizing clinical work practice and business strategic aims was found to be a prerequisite for the design of computerized CPGs, when the aim is to pursue application in real clinical work practice (Paper F).

Conclusion

My findings indicate that guidance of clinical practice has to be provided in a manner that matches the working practice and fulfils business strategic aims. Computerization of CPGs can be a suitable way to provide guidance. However, demands from clinical practice and business strategy have to be scrutinized, prioritized and balanced in the computerization of CPGs. The development and implementation of computerized CPGs may however also entail changes of current clinical work practice.

If computerizations of CPGs are to be more than just a presentation of CPGs and become a true support of clinical work practice, it is essential that the demands from the work practice and the business strategy are thoroughly described and seriously reflected in the design.

The findings in my research are well in line with the recommendations by Bates (Bates et al., 2003), although profoundly expanding the recommendations regarding the design process. Based on my research, I recommend that: (1) work practice and business strategic demands have to be scrutinized as the first steps in the design process for computerized CPGs; (2) it have to be kept in mind that CPGs are providing guidance, not mandatory directions; (3) guidance should be activity specific, presented at the point of care with access to relevant clinical information to enhance compliance; (4) the artefacts applied for presentation of guidance have to fit the working conditions; and (5) it should be possible to make local adaptations of CPGs to match existing work practice and access to resources.

The research in this thesis suggests that computerization of CPGs should be based on the practice applied where the computerized CPG is going to be used. A study of current work practice and workshops with stakeholders on business strategic aims and intended future work practice should form the foundation for the design of computerized CPGs.

Computerization of CPGs should be an integral part of a coherent vision for introduction of IT in clinical work practice, and it should be accomplished in an orchestration of multiple health informatics related competencies.

In conclusion, my short reply to “**RQ1: How is guidance applied in clinical work practice?**” is that guidance is applied from activity specific second order guiding artefacts that are present at the point of care, embedded in the work practice, locally adapted and transformed and that supports coordination.

My short reply to “**RQ2: What kind of demands do clinical work practice and business strategy put on computerization of clinical practice guidelines?**” is that clinical work practice and business strategy put extensive situational demands on flexibility, functionality and features of computerized CPGs, far beyond what can be expressed in a formal representation of CPGs based on an analysis of intrinsic CPG requirements.

Perspectives and future work

My research opens various paths for further work. The following topics appear as the most prominent:

Testing of my findings in other settings

Although solid, my findings should be confirmed by other researchers and by examination of other settings and medical specialties to ensure generalizability, validity and reliability.

Coherent clinical IT systems, including guidance

It was obvious in my research that computerization of CPGs are closely related to the general trend on computerization within hospitals in several ways:

- When computers become a major and integral part of clinical work, it will be obvious that clinical information as well as CPGs applied in clinical practice should be computerized
- Knowledge-based decision-making and planning are profoundly dependent on clinicians' access to relevant information on patients and organizational issues
- Cooperation between various organizational units may be improved by shared standardized work processes. This can be supported by IT systems developed to support CPGs and standardized exchange of information

All this entails that computerization of CPGs is considered an integral part of computerization within healthcare. A more thorough unravelling of clinical work and the clinical demands on guidance and information access is needed to enable the development of systems that can support clinical practice at the point of care.

Development of lightweight methods for clarification of demands from clinical work practice on computerized CPGs

Providing computerized guidance for hospitals is a comprehensive task, where multiple CPGs, should be adapted to multiple various work practice in numerous organisations. Therefore there is a need for developing standardized methods for describing clinical work practice and activities, including the information applied and produced in relation to execution. In the mapping of activities, the examination of activity specific demands on the physical computer artefacts will also be relevant, as I have found that specific clinical situations may put profound requirements on the physical artefacts.

7 Dansk resumé

Det er velbeskrevet at hospitaler har vanskeligt ved at fastholde høj kvalitet og hurtig introduktion af ny medicinsk viden i behandlingen. Kliniske vejledninger er blevet introduceret som et middel til at overkomme disse vanskeligheder. Det er dog også velbeskrevet at anvendelse og efterlevelse af kliniske vejledninger indenfor de fleste kliniske områder er mangelfuld. Computerisering af kliniske vejledninger er blevet fremført som en metode til at udbrede og understøtte anvendelse af kliniske vejledninger. Indtil nu har computerisering af kliniske vejledninger fokuseret på udvikling af formelle præsentationer af de kliniske vejledninger. De udviklede computersystemer har ikke opnået den store anvendelse i klinisk praksis. Den grundlæggende antagelse i denne afhandling er at den manglende gennemslagskraft skyldes en mangelfuld forundersøgelse når der udvikles computeriserede kliniske vejledninger.

Afhandlingen undersøger anvendelse af kliniske vejledninger indenfor områder, som er kendt for en høj efterlevelse af kliniske vejledninger, for at fastlægge krav til vejledning i klinisk praksis og undersøge karakteristika ved de anvendte vejledninger. Bidraget fra afhandlingen falder i to hovedområder:

- En analyse af hvordan vejledning anvendes i klinisk praksis indenfor områder hvor efterlevelse af vejledninger vides at være høj. Analysen fokuserer på at nå frem til generelle krav til kliniske vejledning
- En analyse af krav fra klinisk arbejdspraksis og virksomhedsstrategi, med fokus på krav der har betydning for design af computeriserede kliniske vejledninger.

I min forskning har jeg anvendt observationsstudier, interviews, workshops og indsamling af vejlednings artefakter og vejledninger til dataindsamling. I analyse af data har jeg anvendt en 'grounded theory' tilgang. Yderligere blev udvikling af prototyper anvendt til at validere og præcisere fundene. Til sidst har jeg haft klinikere til at validere resultaterne.

Den empiriske del af afhandlingen består af feltarbejde i tre onkologiske klinikker og et casestudie af avanceret livredning ved hjertestop. Selvom næsten alle patienter indenfor det onkologiske område er behandlet i overensstemmelse med en klinisk vejledning, fandt jeg meget begrænset anvendelse af de fysiske vejledninger og den web-baserede vejledningsportal. Men jeg fandt en omfattende anvendelse af aktivitetsspecifikke fortrykte skemaer og standardordinationer, der var indlejret i arbejdspraksis og præsenterede vejledning på behandlingsstedet. Jeg har konceptualiseret skemaerne og standardordinationerne som anden ordens vejlednings artefakter. Anden ordens vejlednings artefakter er blevet transformeret fra primære vejlednings artefakter (kliniske vejledninger og protokoller) i overensstemmelse med en standardiseret procedure. Ud fra en brugerdeltagelses tilgang er der blevet udviklet prototyper af computeriserede kliniske vejledninger. Disse prototyper er blevet anvendt til at præcisere krav til computeriserede kliniske vejledninger.

Klinikerne i min undersøgelse udtrykte ønske om at have computeriserede kliniske vejledninger, selv om det var en forudsætning at de skulle være let anvendelige og ikke kræve afbrydelser i det kliniske arbejde.

Baseret på min forskning er jeg nået frem til at computeriserede kliniske vejledninger bør være:

- Aktivitetsspecifikke
- Tilstede på behandlingsstedet
- Indlejret i arbejdspraksis
- Fleksible
- Understøtte koordination af arbejdet
- Automatiserede når det er hensigtsmæssigt
- Designet på en måde så det er muligt med lokale tilpasninger
- Designet med fokus på specifikke virksomhedsstrategiske mål

Baseret på mine fund vil jeg yderligere anbefale at design af computeriserede vejledninger baseres på: 1) gennemgribende undersøgelse af arbejdspraksis, 2) formulering af de virksomhedsstrategiske formål og 3) analyse og formalisering af de kliniske vejledninger. Dette indebærer at udviklingsteam besættes med en lang række af kompetencer fra forskellige felter som: sundhedssektoren, virksomhedsledelse, vidensdeling og informationssystemer.

8 Applied abbreviations

ALS	Advanced Life Support
CEG	Computer Executable Guidelines
CDS	Computer-based Clinical Decision Support
CIG	Computer Interpretable Guidelines
CPG	Clinical Practice Guideline
CPOE	Computerized Provider Order Entry system
EBM	Evidence-Based Medicine
IOM	The Institute of Medicine – the IOM is an independent non-profit organization that works outside government to provide unbiased and authoritative advice to decision makers and the public. It is the health arm of the American National Academy of Sciences. Advice from IOM often has a great impact in Europe. For further information see www.iom.edu
PD	Participatory Design
RCT	Randomized Controlled Trials
SOP	Standard operating procedure

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Papers

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- Paper B: Pedersen, B. S., Jeberg, K. A., Koerner, C., Balslev, C., Andersen, P. O., Jensen, M. K. and Lyng, K. M. (2009). IT for Advanced Life support in Hospitals. In Studies in Health Technology and Informatics vol. 143 on Advances in Information Technology and Communication in Health p 429-34, 2009.
- Paper C: Lyng, K. M. Translating clinical practice guidelines into practical clinical guidance artefacts – implications for computerizations of guidelines. In SHI 2009 proceedings p 44-49, 2009.
- Paper D: Lyng, K. M. (2010). From Clinical Practice Guidelines, to Clinical Guidance in Practice – Implications for Design of Computerized Guidance. In Studies in Health Technology and Informatics vol. 157 on Information Technology in Health Care: Socio-Technical Approaches 2010. p 169-174
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From Paper Based Clinical Practice Guidelines to Declarative Workflow Management*

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Abstract. We present a field study of oncology workflow, involving doctors, nurses and pharmacists at Danish hospitals and discuss the obstacles, enablers and challenges for the use of computer based clinical practice guidelines. Related to the CIGDec approach of Pesic and van der Aalst we then describe how a sub workflow can be described in a declarative workflow management system: the Resultmaker Online Consultant (ROC). The example demonstrates that declarative primitives allow to naturally extend the paper based flowchart to an executable model without introducing a complex cyclic control flow graph.

1 Introduction

It has been known for quite a while that there is a need for making clinical working practices safer, as too many errors happen causing suffering or even death of patients [18]. Due to the complexity, the high mobility and ephemerality of the daily clinical work [2, 9] safer working practises will require better coordination, efficient collaboration and not least fulfilment of up to date clinical practice guidelines (CPG) [12, 17].

One way of supporting this is by the use of IT based clinical decision support and better linkages in and among IT-systems [4]. Indeed, according to [21, 19] one of the best options for improvement in clinical work seems to be IT supported clinical processes based on CPG's. However, the use of IT based CPG's is challenging in several ways. Firstly, due to continuous development of new knowledge within the medical domain the mean survival time of clinical guidelines is short, approximately 2 years [26]. Secondly, there is a need for guidelines to be flexible and adaptable to the individual patient [23]. Thirdly, no coherent theoretical framework of health professional and organizational behaviour and behaviour change has yet been established [16]. Finally, it is a serious challenge that health professionals currently tend not to follow clinical

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guidelines [10]. One of the reasons for this could be that clinical guidelines are not embedded in the clinical work processes and the technology available in the clinical setting today. Oncology clinics are an example of a clinical speciality for which it is known that there does exist a high number of CPGs that are followed to a certain degree by the health professionals. For this reason we found it interesting to perform a series of field studies in oncology clinics, to examine enablers and obstacles for use of IT-supported clinical guidelines. The field studies are presented in Section 2 below. Based on the field studies and our examination, we then proceeded to investigate in Section 3 how the current paper based workflows could be supported using a commercial declarative workflow management system, which relates to the CIGDec approach of Pesic and van der Aalst [29]. We believe that the resulting model rather naturally extends the paper based flowchart table used at the hospitals, and in particular avoids the introduction of complex cyclic control flow graphs and over specification as also pointed out in [29]

2 Field Study – Usage of CPGs in Danish Oncology Clinics

2.1 Method

Observations were made on three Danish oncology clinics by two observers (the first author and an assistant). Four days of observation were made at each clinic. Besides observations, access to all clinical guidance material was granted. All the clinics were specialized within oncology; two of them were university clinics. The focus of the observation study was on the use of CPGs as defined by Field and Lohr [15]: “Clinical practice guidelines are systematically developed statements to assist practitioner decisions about appropriate health actions for specific clinical circumstance”. We especially looked at the work of nurses, doctors and pharmacists in relation to chemotherapeutical treatment of patients.

2.2 Overall Treatment Processes and Guidance Documents

Patients are referred to the clinics with a diagnosis of cancer. By the first visit in the outpatient clinic the patient is informed about pros and cons of chemotherapy by a doctor, and an overall patient plan for oncological treatment is outlined. In subsequent visits chemotherapy is given, in between visits to the outpatient clinic monitoring of side effects to chemotherapy are done by laboratory tests. The chemotherapeutic treatment is based on a number of different types of guidance documents and diagrams depicted in Figure 1. The basis of the treatment is given in a standard treatment protocol or a research protocol, which constitute the CPG. The protocols are written in a narrative form with a description of the current knowledge of treatment of the disease in case as well as a thorough description of the drugs to be used. The size of a research protocol is app. 60-80 pages and a standard treatment protocol is app. 30-40 pages. Protocols are generally developed in cooperation between several oncology departments,

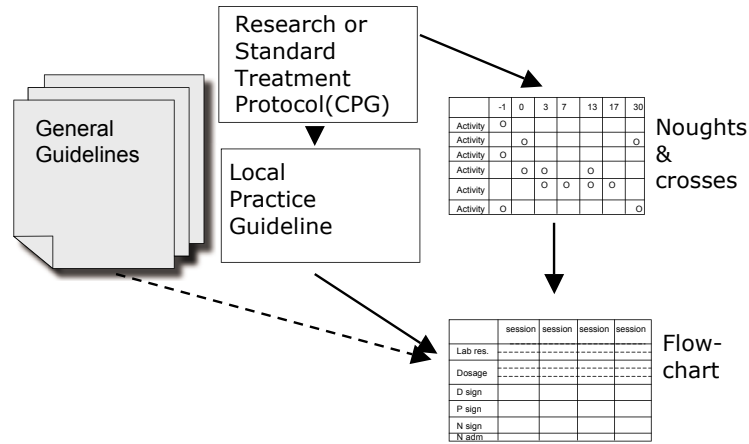


Fig. 1. Overview of the relation between research protocols/standard treatment plans, local practice guidelines (standard plans) and flow charts. General guidelines are in use throughout the hospital, containing issues like the treatment of diabetes.

frequently with a pharmaceutical company as a main sponsor and actor. Research protocols are often multinational. Based on the protocols local practice guidelines (also referred to as standard treatment plans) are made as well as a treatment overview, in daily speech referred to as the noughts and crosses diagram. The noughts and crosses diagram describes the whole pathway including medical treatment as well as examinations during several months. There will often be deviations from the original plan due to side effects to treatment, other medical problems or resource problems in the hospital. The flow of each chemotherapeutic treatment session is guided by the so-called patient flowchart, which also records the state of the treatment session. Below we will describe the workflow resulting from the flowchart in more detail; this will be the focus of the remaining part of the paper.

2.3 Current Workflow for Chemotherapy Treatment Sessions

Fig. 2 shows an overview of the workflow which is reiterated in every chemotherapeutic treatment session. In the flowchart the basic information about the patient is registered, including the latest lab results as well as height, weight of the patient. Based on these informations and the patient history of any major adverse effects, the doctor calculates the therapeutic doses of chemotherapy, documents it on the flowchart and signs it. The flowchart is transferred from the doctor to the controlling pharmacist (who can be situated near by in the clinic or far away in the pharmacy) where it functions as a prescription from the doctor. The controlling pharmacist controls the doctors dosage calculation and writes the information in a working slip that is used for the pharmacy assistant who is doing the preparation of the drug(s) in case. During preparation the quantity of all products as well as batch numbers are registered in the working slip, finally

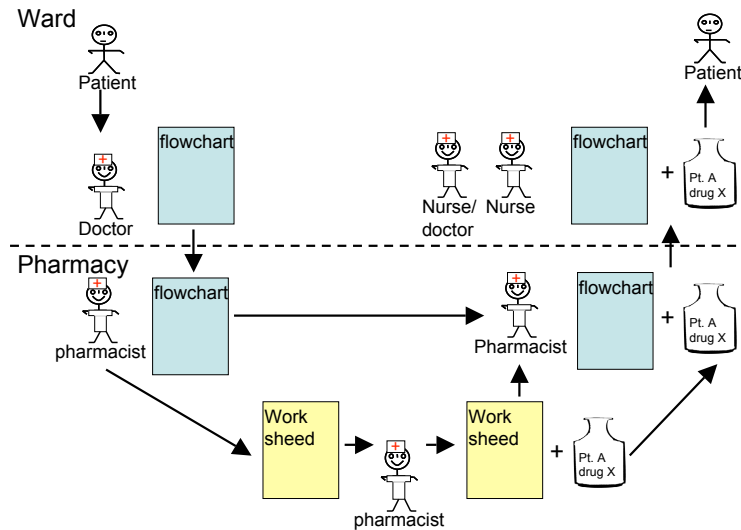


Fig. 2. Oncologic workflow in relation to chemotherapeutic treatment of patient

the working slip is signed by the pharmacy assistant, and the product - usually a drip bottle or a pump with a content and patient information note stuck to it - is referred to the controlling pharmacist for check out. When the controlling pharmacist has checked that the produced drug mixture and patient information note matches the flowchart and the working slip, the pharmacist put small green ticks on each item in the flowchart and finally signs it. Subsequently the flowchart and the product is referred to the treatment rooms, where the responsible nurse together with another authorised person (nurse or doctor) checks that the product and flowchart matches, both regarding content and patient information. The responsible nurse then signs the flowchart and the medicine is administered to the patient. In parallel to this the nurse will administer adjuvant medicine like anti-emetics, cortisol and other drugs that are prescribed in the local practice guidelines. The nurse registers the medication in the Medicine Order and Administration (MOA) IT system that currently is being implemented in all the oncology departments.

2.4 Preliminary Conclusion to the Case Study

Several characteristics of the work were elucidated in the case study:

- There are several professional actors involved in even rather simple workflows like the ones we studied (they are all involved in more than one workflow at the same time).
- The flow is guided by the flowchart, which is simply a table with a column to which the Doctor and Chemist add information and/or a signature, thereby capturing the state of the session.

- The workflow is distributed: the doctor and nurse, pharmacist, and pharmacy assistant are physically located in different places at the hospital and the current paper used for controlling the workflow is physically transferred by a porter or nurse (or faxed) between the different actors.
- Only the actor currently possessing the flowchart knows its state. Much time was used waiting for and controlling the status of the former process step, to be able to plan own work.
- There are a number of check-points. If a check fails (e.g. the Chemist or Nurse doubts the validity of the current state, the previous actors are asked to verify the state and possibly redo a calculation.
- Exceptional events like the medicine getting too old (e.g. if it is not transferred to the treatment rooms and approved within 24 hours) also led to recurrence of activities.
- Only the state (information) and the actors are implicit in the flowchart. The ordering of events (i.e. transfer of the flow chart between actors), handling of exceptions and recurrence/validation of calculations are implicit.

In our observations we found several potential enablers and obstacles to digitalization of the process support, which have been collected in Fig. 3 below.

We believe that IT based process support has a potential in relation to chemotherapeutic treatment of cancer patients. It is though important to be

Enablers	Obstacles
The nurses do a lot of walking between treatment rooms and pharmaceutical preparation rooms to obtain status on the workflow. An up to time status on preceeding process steps would make it easier for the actors down stream to plan work.	Feeling of competence. "I have been here for a hundred years, so I know what to do, and I know the procedures" guidance are not sought for.
Many patients had to follow more than one CPG, due to co-morbidity or adverse effects of treatment	Oral culture problems are preferably discussed with peers, even rather fact based ones.
Meeting legal demands: In the current situation, the pharmacist is lacking a copy of the prescription, which is a legal demand.	No clinical managerial pressure It is not expected than professionals look things up in the existing sources (Paper or IT-based). There is no control (no count on hits)
It was clear from our observations that CPGs and standard treatment plans were more vividly used if they were embedded in the work processes. This could be in the form of documentation templates, automated order forms or decision algorithms.	Rigid work flows that have been founded using low-tech information technology like paper
Many new-commers, as they are more active users of CPGs than those that have been in the job for a longer period. So in departments with a high turn around of employees process support will be more sought for.	Lack of integration between process support and all the clinical information systems, among which some are still not digitalised.
Experience among clinicians that guidelines are hard to find especially IT based ones.	Lack of access to computers, with low response time and single sign on to (all) the clinical IT-systems

Fig. 3. Enablers and obstacles for digitalized clinical process support

aware that such a change in the clinical work is not just a question of giving access to the right applications. Access to the right equipment as well as integrations of it-systems is mandatory. Also the organisational workflows have to be analysed and maybe changed. This demands managerial support. More work has to be done to understand the organisational and social implications. To obtain knowledge about organisational and social implications it is important to establish carefully planned experiments with process support in clinical settings. In the present paper we concentrate on how the workflow of a single chemotherapeutic treatment session may be supported by a workflow management system, and in particular how the workflow can be described as an executable process. A central issue is how to make the implicit ordering of events (and the additional verifications and possibly recurrences of events) explicit. One option is to use an imperative flow graph based notation such as Petri Net or BPMN. However, it would include arrows for capturing the control flow (including cycles for the verification and recurrence of events), which would differ radically from the notation used in the current paper based setting. As suggested by van der Aalst and Pesic in [29] one can avoid introducing the explicit control flow as a complex flow graph by instead using a declarative notation such as the CIGDec model. Following this idea, we will investigate below how to specify the treatment session in a commercial declarative workflow management system, the Resultmaker Online Consultant.

3 Treatment Workflow in Resultmaker Online Consultant

The Resultmaker Online Consultant (ROC) is a user-centric declarative workflow management system based on a shared data store. It uses so-called eForms as its principal activities and allows one to declare the sequential constraints and dynamically included verification steps (and implied recurrences of activities) as found in the oncology treatment workflow using so-called sequential and logical predecessor constraints and a notion of activity conditions. There is yet no formal graphical notation for the ROC processes, but there is a guideline for how to identify and specify activities, roles/actors and constraints in a table of a specific form jointly with the users. This table is referred to as the Process Matrix (PM), which is also used as name for the process model. Figure 4 below shows an example of a PM (simplified to preserve space) for the Oncology workflow presented in the previous section. Each row of the matrix represents an activity of the Oncology workflow. The columns are separated in 3 parts: The first set of columns describes the access rights for the different roles: Doctor (D), Nurse-I (N1), Nurse-II (N2), Controlling Pharmacist (CP), Pharmacist assistant (PA). The next set of columns describes (sequential and logical) predecessor constraints. The last set of columns describes activity conditions. Below we describe the PM for the Oncology workflow and the primitives of the ROC in more detail.

Activities and execution. The notion of an activity in ROC is like in any other workflow language, which means an activity is atomic and corresponds to a logical unit of work. Activities are executed in parallel by default and they can be

S No	Activities	Roles					Predecessors		Activity Condition	Remarks
		D	N1	N2	CP	PA	Seq	Log		
1.1	BASIC_INFO									
1.1.1	Basic info registration*	W	W	R	R	N				patient information like height, weight and surface area
1.1.2	lab. Results *	W	W	R	R	N				Check lab results
1.1.3	Patient history*	W	W	R	R	N				Interview of patient
1.2	ORDINATION						1.1			1.2.2 digitally signs data of 1.2.1 and sets TrustO true.1.2.3 either sets TrustO true or resets 1.2.1
1.2.1	Calculate the therapeutic doses of chemotherapy*	W	R	R	R	N				
1.2.2	Sign	W	R	R	R	N		1.2.1		
1.2.3	Verify ordination	W	R	R	R	N	1.2.2		Not TrustO	
1.3	CONTROL									
1.3.1	Control calculation	R	R	R	W	R		1.2.2		Set TrustO false if ordination not trusted
1.4	PREPARE									
1.4.1	Quantity and batch nr of products are registered*	N	N	N	R	W		1.3.1		This is internal pharmacy work
1.4.2	Sign	R	R	R	W	R		1.4.1		
1.4.3	Check out drip bottle	R	R	R	W	R		1.4.2		1.4.3 resets 1.4.1 if preparation does not match ordination & patient. 1.4.5 resets 1.3.1 or sets TrustP
1.4.4	Sign	R	R	R	W	R		1.4.3		
1.4.5	Verify preparation	R	R	R	W	R	1.4.4		Not TrustP	
1.5	MEDICIN ADM.							1.4		
1.5.1	Check that preparation, order and patient match	R	W	R						The responsible nurse checks together with another nurse or doctor. If it is not trusted either TrustO or TrustP is set to false (forcing the doctor or pharmacist to verify)
1.5.2	Check that preparation, order and patient match	W	R	W						
1.5.3	Sign	R	W	R				1.5.1 1.5.2		
1.5.4	Admin preparation to patient*	R	W	W				1.5.3		

Fig. 4. Information marked with * could be transferred from or registered automatically in another hospital information system (HIS) W= write, R = read, N = denied access

executed any number of times, unless constrained as described below. The state of the ROC records whether an activity has been executed or not. If an activity has been executed, then that activity will have status executed. Its state can be reset under certain circumstances explained in Control Flow Primitives sub section. We say that the flow has state complete at any point where all activities (currently included in the flow, see Activity Conditions below) have state executed. There are the following pre-defined activity types in the ROC: *eForm Activity*: eForms are web questionnaires that have graphical user interface elements displayable in a web browser. The fields on the eForms are mapped to variables in the shared data store and the data filled in by the users will be available to all activities of the workflow instance. eForms are appended to ROC activities in process definitions and at run-time when an eForm activity is executed, the corresponding eForm will be displayed to the user for human interaction. ROC also supports forms developed in Microsoft InfoPath. All activities in the example, except signing activities, are eForm activities. *Invitation Activity*: This type of activity attaches a role to an external user (identified by an email address) and sends an invitation link to the process instance via email notification. (We have not included this kind of activities in the example. In a hospital setting actors should be invited by other means than email.) *Signing Activity*: In order to provide authentication for the data filled in by the users, the ROC uses Signing Activity. The user data on eForms will be digitally signed by using XML digital signatures syntax and users digital identity certificates. A single signing activity supports signing of data from multiple eForms. In the example all the activities named Sign are signing activities.

Resources/Roles: The ROC supports a simple resource model using Role-based access rights to define permissions on the activities to different users of the system. The possible access rights are Read (R), Write (W), Denied (N) and the default access right on activities is Read access. The Read access right allows a user with the particular role to see the data of an activity, where as Write access right allows the user to execute an activity and also to input and submit data for that activity. A Denied access right is the same as making an activity invisible to the user, i.e. the user does not see it as part of the flow. In the example we have used the denied access right to shield the Pharmacist assistant from the rest of the workflow.

Control Flow Primitives: The control flow primitives define the constraints that control the activity execution at runtime. *Activity Condition*: Every activity in the ROC has a logical activity condition. An activity condition is a Boolean expression that can reference the variables from the shared data store. If an activity condition is evaluated to be true, the activity is included in the workflow, otherwise the activity will be skipped. Activity Conditions in ROC workflow model are re-evaluated whenever necessary, so the inclusion of an activity can be changed during the lifetime of the workflow instance. If the activity condition changes to false during the execution of an activity (e.g. when a user is filling in an eForm), the user will be informed that the activity is no longer part of the flow and no data will be changed. This guarantees atomicity of activities. In the example we use two Boolean variables TrustO and TrustP to control the inclusion of the verification actions 1.2.3 and 1.4.5 respectively. When the doctor signs the ordination in

activity 1.2.2, TrustO is also set to true, thereby excluding the verification from the flow. However, it may be set to false during activity 1.3.1, 1.5.1 or 1.5.2. This will force the verification step to be executed and all activities having it as logical predecessor to be reset (see below). *Sequential Predecessors*: If activity A is declared to be a sequential predecessor of activity B, then activity B can only be executed if activity A has state executed. However, the sequential predecessor has only effect if the predecessor activity A is included in the workflow instance: This means, that if the activity condition of activity A at a given point of time is false, then the execution of B will not depend on whether the state of activity A is executed or reset. Sequential predecessor constraints are marked in the Predecessor (Seq) column in the example. For instance, Activity 1.2.2 (Sign) is a sequential predecessor of activity 1.2.3 (Verify), capturing that it does not make sense to verify an ordination if it has not been signed. Also, every activity in the group 1.1 is sequential predecessors of every activity in group 1.2. *Logical Predecessors*: If activity A is declared to be a logical predecessor of activity B, then activity A is a sequential predecessor of activity B with additional constraints: Whenever activity A is re-executed, then activity B is reset. Also, if the state of activity A is reset (as described below), then activity B cannot execute again until activity A has been executed again. Like for the sequential predecessor, the logical predecessor constraint between activities A and B has only effect at the point of times where activity A is part of the workflow instance. However, if a logical predecessor activity A becomes part of the workflow instance after activity B has been executed due to the state changes, then the state of activity B will be reset and hence the activity B must be executed once again. In the example, the verification action 1.2.3 may reset activity 1.2.1 (if the doctor finds out during verification that he needs to recalculate the ordination). This again causes activity 1.2.2 to be reset, since it has activity 1.2.1 as a logical predecessor. To allow for more fine-grained constraints, the ROC workflow model also includes an additional advanced feature called dependency expressions. Dependency expressions are a set of expressions attached to an activity. Like activity conditions, dependency expressions can also contain references to variables from shared data store. However, an Activity Condition evaluates to Boolean values, dependency expression can evaluate to any value. Any change in the value of the dependency expression will change the activity status to reset to indicate that the activity must be executed (at least) one more time (unless it is excluded by the workflow). We have not used dependency expressions in our example.

4 Discussion

It is well known that healthcare processes are complex [13] and although much time is used on coordination [24] errors happens too frequently [18]. CPG's can support healthcare employees in the process of following best practice consistently [17, 27], but it is also well known that impediments to access relevant guidelines is an obstacle for use [28, 14] Thus it seems obvious to embed CPG's in clinical IT- process support, although the success of such projects has not been convincing [19, 1]. In our case study of a rather simple clinical work process we found that the process had an extension in both time and location and

several actors were included. Although the process was frequently repeated there were also frequent alterations and recurrences due to returns to previous steps in the workflow. These challenges could be supported in a natural way by the declarative primitives in the ROC workflow management system. Also, the activity conditions allow smooth combination of several sub-workflows. This would be a way of implementing the noughts & crosses diagram, which indeed specify for each day which sub workflows are relevant. ROC supports the paradigm of embedded although visible CPG's in clinical IT-systems. Though one have to be aware that IT based business support will lay the grounds for new work processes, so one should not just automate existing paper based work processes [7].

Professions, professionalism and process support. In the ROC independent roles can be defined for all actors. The rights to read, fill in, and proceed to next step and to change the flow can defined in relation to each role and activity. This can make it possible for the actors to see the status of the process upstream, and thus make the planning of own work easier. Health professionals are a heterogeneous group, some with little and some with immense experience within a field. Although experience may not totally protect a clinician from committing errors the risk is less and the source of annoyance from detailed guidance by the IT system will be huge. In the ROC focus is on the overall clinical managerial process, for the inexperienced there are links to CPG's outside the ROC. Nevertheless it will be a cultural challenge for clinicians to have a clinical process system directing the road ahead [6], as well as it will have impact on the training and socialisation of new comers to the field [20]. The communication culture in the healthcare sector is profoundly oral [11]. We observed several examples of clinicians discussing factual topics to which the reply only would be a few clicks away. The cultural element will always be a challenge when implementing new technology, especially when it fundamentally changes the work processes [22].

5 Conclusion and Future Work

We have conducted a field study of oncology workflows and mapped a sub workflow into a commercial declarative workflow management system. The restricted use of IT in the places we visited can be due to several reasons, it was although clear that the current IT support was incoherent and did not support the clinical way of working. A more thorough unravelling of the clinical processes and the need for information or opportunity to document is a precondition for succeeding with process support [5]. Even a rather simple workflow as the one we have examined unveiled the need for a business process support application to be integrated to several other of the hospital information systems [19, 5]. Such an integration provides several challenges, both in relation to access control [3] and in relation to semantics [25, 8]. The mapping of the treatment workflow into the Resultmaker Online Consultant demonstrates the use of a commercial workflow model based on declarative process primitives as advocated by Pekic and van der Aalst. The resulting model rather naturally extends the paper based

flowchart table used at the hospitals, in particular one avoids introduction of cyclic graphs. As future work we plan to present the actors at the hospitals for the ROC model and compare it to other approaches, in particular the CIGDec language and imperative languages such as BPMN. We also plan to experiment with prototypes of pervasive user interfaces to the ROC.

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IT for Advanced Life Support in Hospitals.

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Abstract: In this study we have analyzed how IT support can be established for the treatment and documentation of advanced life support (ALS) in a hospital. In close collaboration with clinical researchers, a running prototype of an IT solution to support the clinical decisions in ALS was developed and tried out in a full scale simulation environment. We called this IT solution the CardioData Prototype.

Keywords: Computerised Decision Support, Computerised Documentation, Advanced Life Support. Sociotechnical Design.

Introduction

Cardiac arrest is a hyper acute situation where correct and immediate treatment according to existing guidelines [1] is to be accomplished under a substantial time pressure. This provides two kinds of problems: First keeping clinicians updated with the skills to act correctly when they are in the situation of doing advanced life support and secondly collecting data in the situation for secondary use, so the treatment in the long run can be improved. The incidence of cardiac arrest in hospitals in general range between 1 and 5 events per 1,000 hospital admissions [2]. Reported survival to hospital discharge varies from 0% to 42%, the most common range being between 15% and 20% [2]. There is a need to ensure that the quality of the treatment of patients with a cardiac arrest in hospitals is the best possible [3]; this is reflected in the education of clinical staff at Copenhagen University Hospital Herlev. During training programs conducted in a simulation environment, it is possible to imitate the clinical challenges in resuscitation of a patient suffering from a cardiac arrest and to ensure training to a level of application of the treatment algorithm as described by the European Resuscitation Council (ERC ²). The job of ensuring relevant and necessary documentation during the resuscitation process is another challenge which is related to both legislation and to the collection of data for secondary use in research according to the Utstein Style [4] standard. Our goal for the project was to develop an IT application

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² <http://www.erc.edu/new/>

that could support treatment as well as the documentation during advanced life support (ALS) in hospitals. The needs for decision and documentation support in ALS had previously been investigated as part of a clinical PhD study at Copenhagen University Hospital Herlev where ideas to functionality of an IT system were developed as a paper prototype ³.

The clinical setting

The situation that occurs when a patient in a hospital suffers from a cardiac arrest is a hyper acute event. The staff at the hospital is trained to initiate basic life support with airway support on a facial mask and external thoracic compression right away. There is an alarm system in the hospital activating a resuscitation team: a cardiologist, an anaesthetist, an anaesthesia nurse and two hospital porters. One nurse from the department where the incident takes place is allocated to the team as well. All the team members have dedicated roles on the team. The team is not a stable team; the roles in the team are assumed by those on call in the different departments responsible for the specific roles on the team.

The treatment algorithm and clinical research

The treatment algorithm being used is described in the European Resuscitation Council (ERC) Guidelines for Resuscitation 2005 [1]. It is implemented in Denmark by the Danish Resuscitation Council ⁴. The treatment algorithm includes standard activities, which must be performed, at time intervals of 2 minutes. Decision points are inserted in the algorithm to ensure that treatments are chosen in accordance with the clinical observations; this means that there are different ways to proceed depending on the clinical situation.

One of the most important developments in relation to the treatment algorithm is named The Utstein Style [4] ⁵. This work was conducted in 1997, but is still valid as the basic topic in clinical studies in ALS. The Utstein Style is a consensus among experts on what uniform reporting in resuscitation ought to be, and it gives recommendations for clinical studies in ALS.

Training resuscitation procedures

All staff members in the hospital are trained in initiating basic life support and the resuscitation team members are trained in practising ALS. At Copenhagen University Hospital Herlev the training is conducted at the Danish Institute for Medical Simulation. The training techniques are based on full scale simulation; the only alteration from real life is the fact that the “patient” is a full size electronic doll, connected to a computer. In this simulation setting it is possible to repeat procedures several times, until they are well known, comprehended and applied by all the team members.

³ Unpublished.

⁴ <http://www.genoplivning.dk/>

⁵ Utstein Abbey: Name of the place where the first Utstein Symposium was held at the Norwegian Island of Mosteroy.

1. Methodology

Our methodology was based on participatory design (PD) [5] including observations literature studies, and prototyping.

1.1. Data collection

Based on literature studies we analyzed the external requirements such as the legal demands and the research and development needs related to treatment and documentation of cardiac arrests in hospitals. Based on observation studies in simulation settings, group interviews, and a questionnaire to team leaders we analyzed the internal requirements from the resuscitation teams. The observation studies based on PD were conducted at the Danish Institute for Medical Simulation⁶. The team members we observed were participants in a training program. The simulation setting allowed us to get an impression of the clinical work. Due to ethical issues it was not possible to follow the usual methods in PD, where it is almost obligatory to make observation studies in real life settings. Patients suffering from a cardiac arrest are not able to give their informed consent to our presence at the resuscitation scene as they are unconscious.

1.2. Data processing

The literature study made it possible for us to set up in theory an ideal resuscitation scenario, and afterwards to compare it with our observations from the simulated scenarios. Hereby it was possible for us to identify where the challenges were for the team to follow the treatment algorithm and to do appropriate detailed documentation. Thus we got a supposition on how IT could support the team. In our data processing we used the method Diagnostic Maps [6] to organize our findings. We described the challenges, the possible causative agents, the consequences for the resuscitation team performing ALS, and came up with new ideas for solutions. This method gave us an overview that made it possible to concentrate on ideas to support the team with an IT solution.

1.3. Findings

Our major findings in the observation studies were concentrated on lack of registration of the total time from the collapse of the patient to end of treatment and time intervals according to the treatment algorithm. This was in accordance with the findings in the group interviews and in the questionnaire to team leaders. In our literature studies [3, 4, 7] and interviews we found that in general it was difficult to achieve documentation on an adequate level for clinical use as well as for secondary use (i.e. research).

In the development of the CardioData Prototype our focus was on the match between hardware, software and the working situation. We developed and tested the CardioData Prototype in an iterative process with clinicians from the hospitals resuscitation teams. The tests were conducted in the simulated scenario and based on

⁶<http://www.herlevhospital.dk/menu/Afdelinger/Dansk+Institut+for+Medicinsk+Simulation/In+English>

our analysis of findings and the existing paper prototype. We came up with an Ultra Mobile PC with touch screen, a dedicated simple user interface, so the artifact could be easy to interact with during the stress full working condition while performing ALS.

2. Analysis

The major problems in ALS treatment are difficulties in forming a general view of the situation during the resuscitation, the time management and the ability to follow the treatment algorithm strictly. The most important findings were concentrated on lack of registration of time and time intervals, caused by the very acute and stressful working situation. The consequences of this are primarily the risk of a less effective treatment of the patient as the algorithm is not followed strictly. As a secondary consequence it will be difficult to collect data for research and quality improvement. We found that some of the time registration challenges and the need for a clinical overview obviously could be solved with an IT solution. We also found it possible to support decisions concerning ALS treatment.

In the ALS setting there will always be a defibrillator. There are many different brands, but most of them support the time management and to some extent other functions for example data collection. But the user interface is often too complex in a resuscitation setting. Support functions like conversion to child dosages are not integrated in defibrillators; neither is the ability to exhibit a treatment summary while still performing ALS. Ideas of using some kind of voice or sound response to support the team was analysed, but our observation studies and interviews showed a very complex environment of noises and the clinicians were not interested in bringing more noise into the resuscitation scene.

3. Results

The CardioData Prototype supports time intervals defined by the treatment algorithms, chest compression rates and ventilation procedures. By default it supports treatment of adults, but it is possible to choose a user interface that can support resuscitation of children of various weight intervals. It supports documentation of defibrillation, as well as collection of data and re-evaluation of the patient during ALS. It also supports documentation of various medications and intubation of the patient. When the resuscitation is terminated, it is possible to send the collected data to a database, for example the local electronic health record. The functionalities behind the user interface of the CardioData Prototype are listed in table 1. These were the features of ALS that we found meaningful to support with IT.

The tests we performed, using the CardioData Prototype in the simulation training session was very successful. The clinicians found the functionalities useful and supportive for both decision making and documentation. The primary challenge is to find the right person on the team to control the CardioData Prototype. Sociotechnical design including design of work practice is an important issue. We tested it both with the two hospital porters and with the team leader (the Cardiologist) and it seem to be the hospital porters who maintain the best overview of the situation and by controlling

the CardioData Prototype they are able to keep track of time and to support the work of the rest of the team.

Table 1: Functionalities in the CardioData Prototype

Start and restart	It is possible to restart the CardioData Prototype, if the same patient gets another incident of cardiac arrest
Algorithm for adults	Default setting in the user interface
Algorithms for children	Options to choose treatments within weight intervals for every 5 kilograms
The total time	The total time from the CardioData Prototype is turned on is registered
The cardiac rhythm, defibrillation and time intervals (2 minutes)	<p>The result of the observation can be documented as shockable- or non-shockable cardiac rhythm.</p> <p>The amount of Joule to be delivered is indicated on the button.</p> <p>A clock counts down 2 minutes from the last rhythm observation registered and supports the treatment algorithm.</p>
Cardiopulmonary Resuscitation	<p>Before intubation of the patient: "30:2" - this refers to 30 thoracic compressions alternating with 2 ventilations</p> <p>After intubation it changes to continually thoracic compression and ventilation</p> <p>The ventilation rate and the compression rate is visualised with icons</p> <p>The icon changes rate according to whether the patient is intubated or not.</p> <p>The time of intubation can be documented</p>
Medication administered	<p>Adrenalin 1 mg, Atropine 3 mg, Amiodaron 300 mg</p> <p>Other medication administered</p> <p>If "child" is chosen, the dosages shown on the buttons are following the weight intervals</p>
Summary	<p>Spontaneous circulation. The button is activated when a spontaneous circulation is achieved, and it terminates the total clock.</p> <p>Summary or termination. The button is activated if the team needs a treatment summary during the resuscitation. A new window is opened and shows a list of the treatment with an exact time log. When the resuscitation is terminated, it is possible to send the collected data to a database</p>

4. Discussion

The primary strength of the CardioData Prototype is the support of the documented relevant functionality and doing so through a simple user interface. The functionalities in the CardioData Prototype are developed to support primarily decision making for the team leader, but also to keep track of time and time intervals under stressful working conditions. The collected data can secondarily be used for research.

The main challenge in the prototyping process was to design a user interface that is simple and intuitive, as it is to be used in a life critical setting by persons who perform ALS infrequently and under urgent conditions. It is also a challenge to support resuscitation teams that are put together ad hoc. Due to this, only the functionalities we

found most important are displayed in the user interface in order to keep it simple; we refrained for example from medications that are rarely used.

The CardioData Prototype is still an early prototype and it is not yet being used in a real life setting. At the moment it is being tested as a device to ensure the quality of training at the Danish Institute for Medical Simulation. The primary results are very promising and the instructors and clinicians are very satisfied with the use of the CardioData Prototype in this setting. The CardioData Prototype makes it easier to give feed back on the test scenarios for resuscitation; this includes observation and comparison of the thoracic compression rate and the ventilation rate. In the training situation it is the instructor who controls the CardioData Prototype. Optimizing the user interface design is still an issue, as well as the challenge of how to optimize the use of the CardioData Prototype and the relation to the other technical devices apparent in the situation. It is a disadvantage to the CardioData Prototype that it is not yet connected to the monitoring of time in the defibrillator; that would give a possibility to connect clinical events to the cardiac rhythm “on-line”. More tests and sociotechnical design needs to be performed to clarify who in the resuscitation team should control the CardioData Prototype. It is still considered whether other user interfaces could support the team work in a better way, for example by projecting the user interface on a wall or screen, so it is visible for everyone on the team.

5. Conclusion

We developed and afterwards tested the CardioData Prototype as close to reality as possible at the Danish Institute for Medical Simulation. The test persons were real clinicians with experience in Advanced Life Support. The clinicians’ evaluation was positive. We find it important to continue the development and testing of the CardioData Prototype so it can be developed for use in a clinical setting. We found the modified PD method very useful in the development process. Our work contributes to the research in the field of how to optimize the resuscitation paradigm as well as it contributes to studying clinical work in a hyper acute setting in a simulation environment. Further development is necessary, thus the collaboration is continued to ensure this.

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Translating clinical practice guidelines into practical clinical guidance artefacts – implications for computerizations of guidelines

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Abstract

Much effort has been put into developing clinical practice guidelines (CPG's), but still the clinical adherence and thus the clinical effect of CPG's is limited. During the last decade computerization of CPG's as a method for propagation and dissemination of CPG's have been tried out. Most of the computerization of CPG's has been conducted as workflows. In this paper an observation study of the use guiding artefacts in clinical practice in three oncology clinics is presented. It was observed that although the application of voluminous traditional narrative CPG's was scarce, a broad variety of guiding artefacts were applied in daily clinical practice. The majority of the guiding artefacts applied was related to specific tasks or closely integrated to documentation in relation to the task. Thus it is proposed that computerization of CPG's should not only focus on workflows, but be conceived as an integrated part of a coherent vision for introduction of IT in clinical work.

Keywords:

Guideline, guideline adherence, computer system, knowledge bases.

Introduction

During the last two decades much effort has been put into development and propagation of clinical practice guidelines (CPG's)[1]. According to Field and Lohr[2] *CPG's are: "systematically developed statements to assist practitioner decisions about appropriate health actions for specific clinical circumstances*. The actors in relation to and the motives for developing and disseminating CPG's are multiple[3-5]: CPG's are developed as:

- A tool for clinical managers to regulate quality of care and avoid errors and unintended variation
- A tool for administrators to support efficiency and cost cutting of clinical work
- A way for professional societies to consolidate professional autonomy
- A way for clinicians to deal with the continuous growth in medical knowledge
- A prerequisite for obtaining accreditation by an accreditation body

The differences in scope and variety of stakeholders have led to a variety in CPG expressions, although guideline authors are encouraged to employ rigorous formal techniques, to ensure syntactic, logical and medical validity of CPG's[6].

Although the aim of CPG's is to influence clinical practice non-adherence to CPG's still is a major problem[7, 8] and the effect of CPG's on clinical outcome is still dubious[9]. There is a variety of reasons for non-adherence to CPG's, some of which are cultural [10, 11], or due to disagreement with the CPG's while others are unawareness of CPG existence, lack of time for reading CPG, inability to change habits[9]. Thus computerization of CPG's providing just in time guidance has been proposed as a way to overcome some of the problems with non-adherence to CPG's^[12-16]. The first reports on computerization of guidelines are very promising [15, 17, 18], focus has though mainly been on establishing IT-supported patient workflows based on CPG's.

Computerization of CPG's

Computerization of guidelines can in principle be conducted by two types of approach either as model-centric or as document-centric[19]. In the model-centric approach a conceptual model is defined by domain experts, while in the document-centred approach mark-up based tools are used to systematically mark up the original CPG to provide a semi-formal model from the text.

Several groups have developed formal languages to model computer-readable or computer-interpretable CPG's, such as Arden Syntax[20],[21] Asbru[22], EON[23], GELLO[24], GESDOR[25], GEM[26], GLIF[27], GUIDE[28], PRODIGY[23], PROforma[29] and Protege[30, 31]. Focus in the mentioned formalisms has mainly been the to present the CPG's as workflows. Although CPG's concurrently holds a wide variety of other kinds of information, like information on why and how clinical work should be carried out. We have thus found it of interest to examine what kind of guiding artefacts that are currently used in clinical practice, focussing on the implications for computerization of CPG's

Materials and Methods

Observations of CPG usage were made in three Danish oncology clinics during the first quarter of 2008, by two observers (the author and an anthropologist). Four days of observation were made at each clinic. Besides observations, access to all clinical guidance material was granted. All the clinics were specialized within oncology; two of them are university clinics, the last is situated in a large central hospital. In all the clinics computerised patient administration systems (PAS) as well as CPOE for laboratories had been in use for decades. A medication administration and order entry application was under implementation and an add-on module to the PAS-system for physicians' notes were being introduced during the observation period. All clinical staff was provided with access codes and passwords for the relevant clinical applications. Computers were accessible in all offices, including the examination rooms in the outpatient clinic.

The focus of the observation study was on the use of CPG's as defined by Field and Lohr[2]. Thus multi-organisational standard-treatment guidelines and research protocols are interpreted as CPG's. After the observations the results were presented at meetings in the two university clinics (the non-university clinic dropped out due to change of management), finally workshops were held in the university clinics focusing on how clinical practice guidelines may be computerized.

Results

Although it was known to the observers in advance that close to all patients within oncology are treated according to CPG's either in the form of standard-treatment protocols or research protocols, we were only able to observe very scarce active deployment of CPG's. The only tasks where we were able to observe frequent deployment of CPG's were in relation to prescription of medication.

It was obvious that it is not a prominent part of the clinical culture to apply CPG's as we observed frequent discussions of factual subjects, where we were able to find relevant CPG's and we never observed a senior asking a junior whether he or she had looked up a topic or what to do in a CPG. Nor where there any counter on the electronic CPG database, so nobody knows whether it is actually used or not. The junior doctors where complaining that although there are computers in all offices and out-patient rooms, there were situations where they did not have access while needed; in the patient-rooms at wards and in the acute reception area.

In each department there is a team that is responsible for translating and transforming national or multinational CPG's to local guidelines and guiding artifacts. In all the departments there is a standard operating procedure for applying and translating national or multinational CPG's. It has become a tradition to do it in each department, as the departments have individual responsibility for printing forms, checklists, documentation templates and other material.

The people we talked to in the teams responsible for transforming national or multinational CPG's conceded that it could be beneficial to do the translation and transformation in cooperation, and in fact most of the materials produced by the teams are rather similar.

In all the departments a wide number of documentation templates and schemata were developed based on the CPG's.

What to do: <ul style="list-style-type: none"> • <i>Chemotherapy administration</i> • <i>Pre-defined anti-emetic cure</i> • <i>Pre-chemotherapy blood tests</i>
When to do what: <ul style="list-style-type: none"> • <i>Overview flowchart for a treatment protocol</i> • <i>Anti hormone treatment for specific diagnosis</i> • <i>Handling of leucopenia after chemotherapy</i>
Procedures: <ul style="list-style-type: none"> • <i>How to inform a patient prior to chemotherapy</i> • <i>Nutrition management</i> • <i>Managing a permanent intravenous catheter</i>
Calculations and classifications: <ul style="list-style-type: none"> • <i>Calculation of chemotherapy dosage</i> • <i>Reduction of dosage based toxicity symptoms</i> • <i>Nutrition risk evaluation</i>

Table 1 Examples of schemata and templates observed in use.

These templates were typically including both guidance on what to do, and room for documentation, and we observed that these templates were very vividly used in the daily work. In Table 1 examples of the most commonly used templates and schemata are listed.

Facilitators for use: <ul style="list-style-type: none"> • <i>Guidelines integrated in the clinical IT-systems</i> • <i>Guidelines integrated in work process artifacts</i> • <i>Predefined templates</i> • <i>Easy access</i> • <i>In-experience/newcomers</i> • <i>Legal demands</i>
Obstacles for use: <ul style="list-style-type: none"> • <i>Feeling of competence</i> • <i>Oral culture</i> • <i>Experience that guidelines are hard to find.</i> • <i>No managerial pressure</i> • <i>Ignorance of the existence of CPG's</i> • <i>Lack of integration between CPG and clinical information systems</i> • <i>Lack of access to computers in working situations</i> • <i>Time constrains on tasks</i>

Table 2 Facilitators and obstacles for use of CPG's in daily clinical practice

A broad number of the guiding artifacts in use related to one or few task providing very specific guidance. Opposed to this type of guidance are the overview flowcharts that provide an

overview of the whole recommended patient trajectory extending weeks to several month. A characteristic of the flowcharts is that tasks have temporal relations to other tasks, and that tasks reoccur.

Beside the schemata, templates and flowcharts there was a vivid use of standard orders for the laboratory and medication. Although these standardized order packages were not perceived as guiding artifacts by the clinicians.

While analyzing our observations a variety of topics that either facilitated or obstructed the active use of CPG's in daily practice was disclosed, the main facilitators and obstacles observed are listed in Table 2

As the final part of the study workshops were held with clinicians (both doctors and nurses) in both of the university clinics. The results from the observations were presented together with different approaches to computerization of CPG's, and the clinicians were asked whether they would like to enhance the usage of CPG's in daily practice, and if they would what kind of access to guidance they then would like to have. The main wishes for guidance of clinical work are listed in Table 3.

- *Speedy provision of relevant guidance*
- *Single sign-on*
- *Overview of the patient trajectories*
- *Access to relevant - activity specific - information*
- *Process support - reliance that orders are executed*
- *Automation of ordering process*
- *Decision demands - reminders on need for evaluation/decision during a patient trajectory*
- *Possibilities for registration of deviations from a plan*
- *Flexibility in presentation and process*
- *Supporting clinicians and patients mobility*
- *Intuitive user interface*
- *Avoid redundancy of information*

Table 3 The main wishes for guiding support of clinical work expressed by the clinicians during workshops

The two workshop groups ended out in nearly the same topics; for both groups speed and easiness of access to relevant guidance were the most relevant topics. It was also clear that providing IT based guidance is closely integrated to the development of other clinical IT applications, as the clinicians does not distinguish between the different clinical applications but refers to the bulk of applications as an integrated application that can provide clinical process support.

Discussion

Computerization of CPG's seems to be a very efficient way of disseminating CPG's and may thus also be a way to ensure better adherence to CPG's[32]. The facilitators for CPG deployment are very closely related to the ease of obtaining guidance, this corresponds very well with the recommendations given by Bates[33] and the wishes expressed in the workshops. One of the main obstacles is the mismatch be-

tween very voluminous CPG's and the clinicians time constrained ephemeral[34]work practice where tasks are to accomplished in rapid order, The ephemerality with rapid turn-over of tasks provides very limited time to concentrate on a single task and subsequently not time to look anything up.

The guiding artifacts that are deployed in today's clinical practice has been developed in close relation to the daily work practice over a period and can thus be seen as an expression of the clinical needs for guidance under the current socio-technical conditions. Some of guiding artifacts appear in a very technology dependent way; e.g. is closely related to the use of a paper template for documentation of a certain task, while others are more dependent on the way the work is organized e.g. like how the work is divided between actors. Thus there is a risk of loss of guidance while moving from low-tech paper based documentation to IT-applications. On the other hand holds introduction of IT an opportunity to provide quick, specific and relevant guidance to clinical work, as sought for by the clinicians in the workshops we did hold.

A characteristic of a wide proportion of the guiding artifacts that we observed in use is the close relation to a single task and the documentation in relation to the task. The ease of carrying around a single sheet of paper that could be used for documentation and at the same time serves as a sign of workflow status. Like it was the case with the chemotherapy administration sheet that served as a supporting tool for the cooperation between the doctor, nurse and pharmacist, carrying both information on what should be done, the actual documentation of what was done and the legally demanded signatures of the actors. It is though technically possible to develop declarative guidance tools with integrated dynamic documentation[35].

Standardized clinical workflows are just one way of computerizing CPG's, but not all guidance can be presented as a workflow[36]. Thus there is a need for developing standardized ways of presenting other types of guidance, in a way that match the clinical working situations. While doing this it is important to be aware of the characteristics of clinical work where the ephemerality and mobility provide demands that difficultly can be fulfilled by classical computer work stations [37].

Computerization of CPG's can be a very efficient way of providing clinicians with just in time guidance, but this demands the capability of monitoring the clinical processes and providing contextual information for the CPG's, so only the specific guidance is presented to the clinician. To be able to do this there is a need for standardization of clinical documentation, so the relevant information on the current context can be provided to the CPG execution engine[38].

Currently there exists a wide variety of models for computerizations of CPG's [14]. There is a need for developing standardized methods for describing clinical tasks and processes including the information needed and produced in relation to the execution of the task/process. Guidance on what to do, when to do it, and how to do it may then be provided in a spe-

cific, precise and timely manner supporting the clinicians in their work.

Conclusion

We set out to study the use of CPG's with the aim of discovering if, and in case how CPG's can be IT supported and found that practical clinical guidance is very closely integrated to the interception and presentation of clinical data. Thus providing relevant clinical guidance to clinicians will demand integration to most of the patient care information systems to be able to provide contextual information to ensure relevant guidance and to provide the clinicians with the relevant information to be able to make decisions and perform tasks based on best current knowledge.

Computerisation of CPG's could be a beneficial way to support clinicians with relevant guidance. But computerization of CPG's should not be conceived as a free standing task, but as part of the coherent vision for change [39], while introducing IT support for clinical work.

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From Clinical Practice Guidelines, to Clinical Guidance in Practice – Implications for Design of Computerized Guidance

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Abstract. This paper presents a case study of clinical guidance within oncology clinics. Close to all patients treated within the observed clinics were treated according to a research or standard treatment protocol. The protocol artifacts were however rarely applied in clinical practice instead we found an extensive application of what we have named second order guiding artifacts. The deployed protocols underwent a local adaptation and transformation process when initiated. The protocols were adapted to match the local resources and transformed into several activity specific second order guiding artifacts. The transformation from protocols was executed according to a standard operating procedure. Each activity type had a standardized template ensuring uniformity across second order guiding artifacts within a clinic. The guiding artifacts were multi-functional and a wide variety of standardized graphical attributes were applied to support effortless appliance. The implications for computerization of clinical practice guidelines are discussed.

Keywords. Clinical Practice Guidelines, Health Information Systems

Introduction

In the last decades Electronic Health Records (EHRs) have been introduced in hospitals with the purpose of improving the quality of care¹ [2]. Concurrently Clinical Practice Guidelines (CPGs) have been extensively introduced, for the same reason [3]. CPGs can be defined as: “*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*” [4]. CPGs may provide both support for decision-making in relation to care of a patient and process support for planning of care activities. CPG application has however not been comprehensive in clinical practice [5, 6] as well as the demonstrated impact of CPGs on clinical outcome is scanty [7]. Therefore attempts have been made on promoting computerized CPGs as part of the computerization within hospitals. CPGs have been computerized either as computer interpretable guidelines (CIG) [8], computer executable guidelines (CEG) [9] or integrated to the EHR [10]. However none of the systems are presently comprehensively applied. Most

¹ Quality of care includes effectiveness, efficiency, patient orientation, timeliness safety, and equity [1]

computerizations of CPGs have been technology driven [9]. Applying a more user-centered approach in the design may help overcoming some of the obstacles for application in practice [11].

Within oncology close to all patients are treated according to a CPG. Therefore we have found it of interest to study how CPGs are brought into clinical practice within oncology and to analyze the implications it may have for computerization of CPGs.

1. Methods

Protocols are a special type of CPGs, providing recommendations for a specific cure for a specific disease. Protocols have its origin within clinical research, where research protocols provide a detailed description of aims and activities in a research project. When a scientific study is over and the examined cure has proven superior to existing treatment, it has become a tradition within oncology to remove all research specific parts and turn the protocol into a standard treatment protocol. Standard treatment protocols are thus less comprehensive than research protocols both regarding format and content. Protocols include a standard patient pathway for the disease in case. 20-25% of the patients within oncology are treated according to a research protocol, the rest are treated according a standard treatment protocol.

1.1. Methodology

An observation study of guideline usage was made in three Danish oncology clinics in spring 2008. Two observers (a physician (the author) and an anthropologist) each made two full days of observations in three oncology clinics, all in all 12 days of observations. Two of the observed clinics are situated in large university hospitals, and one clinic in a big regional hospital. The application of guidance was observed and ad-hoc interviews were made with end-users. Further interviews were made with those who where responsible for transforming protocols into the guiding artefacts applied in practice. In analysis of the data material the following steps were taken: familiarization with material, identification of keys issues, indexing of data, charting and mapping and finally interpretation [12]. In all the clinics computerized patient administration systems (PAS) as well as CPOE for laboratories have been in use for decades. A medication- administration-and-order-entry application was under implementation and a module for physician's notes were being introduced during the observation period. Computers were accessible in all offices, including the examination rooms in the outpatient clinic but not in the treatment rooms. All clinical staff had access to the clinical IT systems.

2. Findings

We found that in clinical practice CPGs and protocols were scarcely deployed [13]. However, we found comprehensive application of what we have named second order guiding artifacts; forms and standard order sets that have been transformed from CPGs and protocols according to a standard operating procedure (SOP).

2.1. Transformation of protocols to second order guiding artifacts

All the clinics have a research or project unit, staffed with experienced oncology nurses, where research protocols and standard treatment protocols are managed. There is an articulated standard operating procedure (SOP) for starting up of a new protocol. When a new protocol is brought forward a preliminary ‘treatment and examination’ form is made, presenting an overview of activities = resource consumption. This form constitutes the basis for a managerial decision on rejection or initiation of the protocol. Initiation will often include adaptations to local work practice and resources. When adaptations are carried out the project nurse subsequently start the transformation of the protocol into second order guiding artifacts according to the SOP. During the transformation process the project nurse consult relevant actors for discussions of details in the configuration of the second order guiding artifacts. An overview of the adaptation and transformation process is provided in Figure I.

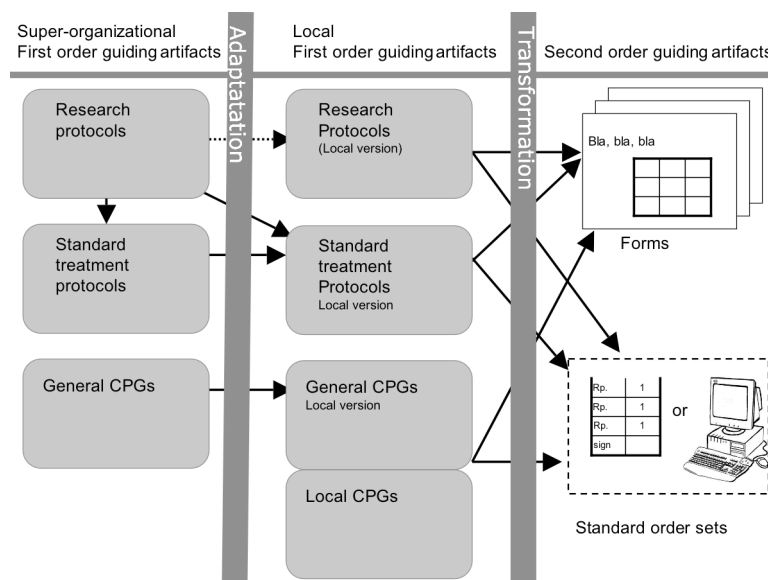


Figure I Overview of the adaptation and transformation process applied when treatment protocols are initiated. The broken line between the research protocols indicates that adaptation of research protocols are minimal, as one have to comply with the research set-up to comply with the protocol. The merger of CPGs indicates that it may be difficult to differentiate between profoundly adapted CPGs and locally developed CPGs.

In the transformation process protocols were chopped into bits matching specific clinical activities, each bit was providing guidance on a specific activity. A protocol may in one chapter state how chemotherapy should be administered, in another chapter there may be information on monitoring and in a third place (protocol or a CPG) there may be information on what kinds of adjuvant therapy that should be administered in relation to the chemotherapy. All these bits of information were in the transformation process brought together in one guiding artifact to support the specific activity.

All protocols where found to have the same types of second order guiding artifacts. The second order guiding artifacts were activity specific. This implied that forms were developed for a specific clinical activity like ‘start up’, ‘treatment and examination overview’, ‘ordering of chemotherapy’, or ‘toxicity classification’. For standard

protocols there were 7-10 forms, for a research protocol there was additionally 10-12 forms. In praxis a standard treatment protocols may be constituted only of a set of second order guiding artifacts. The applied second order artifacts were continuously sophisticated based on an on-going dialogue between the project nurses and the clinicians. Although the majority of protocols were applied in all the observed clinics, the second order guiding artifacts were all transformed locally. The types of second order guiding artifacts were found to be close to similar in all the clinics, although variations in the organization of work entailed some differences. It was however stated by the project nurses that it would be possible and maybe even desirable to exchange forms as they were based on the same protocols and the clinics already were cooperating in different ways.

2.2. Characteristic features applied in second order guiding artifacts

The second order guiding artifacts were designed to provide clinicians with an overview of *appropriate healthcare for a specific clinical circumstance* at a glance. The paper forms were kept as one sheet of paper often printed on both sides. A wide variety of standardized features were applied in the design of second order guiding artifacts— see Table I to ensure a unique presentation of the artifact.

The second order guiding artifacts were found to be activity specific and support several aims like guidance and documentation concurrently [14]. Second order guiding artifacts were due to the portable format present at the point of care and due to the support of multiple aims they were deeply embedded in the work practice.

Functionality and features	Example
Decision support	<ul style="list-style-type: none"> - Table for calculation of dosage based on surface area - Tables for classification of adverse effects
Process support	<ul style="list-style-type: none"> - Overview of standard treatment and examination plan - Monitoring schema for chemotherapy infusions
Standardized templates for documentation	<ul style="list-style-type: none"> - Check boxes - Vital values - Signatures
Physical presentation	<ul style="list-style-type: none"> - Colored paper forms, with dedicated colors for specific activities - Standard order sets integrated in CPOE
Graphical features	<ul style="list-style-type: none"> - Standardized positioning of information - Tables - Water marks
Typographical features	<ul style="list-style-type: none"> - Font size - Bold - Underlining

Table I. Overview of functionalities and features commonly applied in second order guiding artifacts

The second order guiding artifacts supported both decision-making like dosage calculation and process tasks like planning of activities. A good part of data in relation to management of chemotherapy was only registered in a form. The forms were thus archived like medical records.

3. Implications for computerization of CPGs

There is an imperfect evidence base informing decisions on how to translate medical knowledge into routine practice [5]. However within oncology there is a tradition for practicing according to protocols that holds the current best medical knowledge, therefore it is an obvious place to study the translation process. The protocol artifacts were however not found to be deployed in clinical practice; instead a large number of second order guiding artifacts transformed from protocols were observed in action [13]. Second order guiding artifacts are designed to support a specific activity at the point of care and are profoundly embedded in the work practice. This finding is in good accordance with others who argue that presentation of relevant guidance at the point of care is a suitable way to obtain desired behavior [15, 16].

Substituting the observed second order guiding artifacts with computerized guidance entail a series of challenges. In order to support computerized activity specific guidance there is a need to develop activity aware systems [17]. This will imply sensors for activity recognition [18] as well as pervasive computing [19]. In the observed second order guiding artifacts a large number of features were applied to make the artifact activity specific (see Table I). Each artifact had some characteristic functionality and features. To substitute this in a computerized solution development of activity specific interfaces will have to be developed [20]. Activity specific guidance and room for documentation were freely intermixed in the second order guiding artifacts. This is in good accordance with clinical practice, where tasks are mingled although it violates the current concept of task specific information systems.

The second order guiding artifacts did hold both decision and process support [21, 22]. The decision support was typically presented as a table for classification or as calculation tables reliant on patient data. Process support was outlining recommended activities in standard pathways. Both types of support put heavy demands on application logic and semantic interoperability [23] when computerized.

The project nurses were unconsciously applying a participatory design approach in the process of transforming protocols into second order guiding artifacts. This is a suitable and well established method for design of tools for work process support [24]. The continuously ongoing sophistication of the second order guiding artifacts implies that there will be a need for end user development [25] if the current guidance are to be substituted by computerized solutions.

Clinical practice is complex thus it is no surprise that complex tools are required to support it. It can be discussed whether all second order guiding artifacts have to be substituted by computerized solutions. However growing demands on evidence based care and transparency of care will require computerized solutions for support of clinical work [1].

4. Conclusions

Computerization of CPGs for application in clinical practice is a complex job. Examination of how CPGs currently are brought into practice may though give some hints on how to do. Comprehensive narrative CPGs are not applied in clinical practice. Instead numerous activity specific second order guiding artifacts that have been adapted and transformed to the local context are applied. An important issue in my findings is that a wide array of functionality and features are applied in the

transformation. Cooperation across a wide range of research areas will therefore be required to be able to computerize CPGs.

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Guiding artifacts in clinical practice – implications for computerization

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Abstract

Objective: Much effort has been put into the development and publication of clinical practice guidelines (CPGs) to promote effectiveness, efficiency and safety within healthcare. The application of CPGs in clinical practice are however deficient. Computerization of CPGs has been proposed as a method to promote application. Computerization of CPGs has until now focused on formalization of CPGs and have only had a limited impact in practice. This study sets out to examine application of CPGs in clinical practice, focusing on implications for computerization.

Methods: An observation study on the application of guidelines in clinical practice within oncology was made. The observation study was supplemented with interviews and collection of guiding artifacts. Further workshops were held with clinicians defining requirements for guidance in daily work practice.

Results: Textual CPGs were rarely used. However, we found comprehensive application of numerous forms and predefined order sets that we conceptualize as second order guiding artifacts. Second order guiding artifacts have several characteristics: they are locally transformed from textual CPGs according to a standard operating procedure, they are activity specific, present at the point of care, embedded in the work practice and support coordination in clinical practice

Conclusion: The functionality and features of the applied second order guiding artifacts should be taken into account when computerizing CPGs. This implies that local adaptations, activity specific support, presence at the point of care integration into work practice and coordination support, are dealt with in the design of computerized CPGs.

1 Introduction

The knowledge base within healthcare continues to improve [1]. However, clinical practice continues to lag behind and problems with quality of care and frequent errors are realized [2-6]. To a large extent, the problems can be referred to inability to bring new knowledge into clinical practice [7]. The most common way to present new knowledge for clinical practice is in the form of clinical practice guidelines (CPGs). Thus, the volume of published CPGs has proliferated extensively during the last decades [8]. According to Field and Lohr, CPGs can be defined as: “*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*” [9]. Much effort has been put into the development of CPGs [10]. Implementation, though, is often left to some kind of passive diffusion [11], although it is well documented that the passive diffusion strategy is inexpedient [12, 13]. The passive diffusion strategy contributes to problems with non-compliance [14] and lack of impact [15].

Several authors recommend that theory based and multi-faceted approaches for implementation of CPGs should be applied [16-18]. Computerization of CPGs is an obvious new facet in a multi-faceted implementation strategy, well in line with the fact that hospitals are currently experiencing a wide-scale introduction of clinical IT [19, 20].

CPG computerization can be accomplished on several levels of automation [21] from basic storage and search facilities for CPG documents in knowledge management systems [8] to computer readable CPGs [22, 23], and ultimately computerized execution of CPGs [23-25]. The majority of CPG computerizations have been made either as workflow systems [26] or as computerized decision support algorithms [27].

Even though CPG computerization has proven to have a beneficial effect on process outcome [28] as well as on patient outcome [29, 30], the systems have not gained any vivid application in clinical practice [24]. This is so even though there has been much focus on the introduction of clinical IT as a tool for improving quality of care [31, 32]. Some of the problems can be ascribed to designs unsuitable for the complex work practice within hospitals [33]. We argue that one reason for this is that design of CPG computerization has been accomplished from a technology perspective rather than from a computer supported cooperative work (CSCW) perspective. The main aim in the current computerizations has been to develop formalisms for presentation of CPGs [34] not to provide guidance sought after by clinicians.

Therefore, we have set up a study to examine present use of CPGs in clinical practice and clinicians' demands for clinical guidance. The usages of clinical guidance in three oncology clinics were examined. The oncological specialty was chosen because of the long tradition for extensive application of CPGs in the form of research and standard treatment protocols within the specialty [35]. Observations of practice and interviews with end users are known to give rich and detailed domain knowledge that is highly relevant when designing IT systems [36, 37]. The study objective was to examine and explore how CPGs and protocols are applied in clinical practice, identifying functionality and features that it would be advantageous to sustain when computerizing CPGs. By thoroughly analyzing the present functionality and features, we have been able to define corresponding opportunities for design of computerized CPGs. This approach has helped us formulate recommendations for how computerization of CPGs should be designed to support application in clinical practice.

2 Methods

The study was conducted as an observation study, by the author – a physician - and an anthropologist. We both made two full days of observation in the same three oncology clinics, all in all twelve days of observations were carried out. The observations were supplemented by ad-hoc interviews whenever feasible and collection of textual CPGs and other kinds of guiding artifacts.

2.1 Study sites

The study took place from January to October 2008 in three oncology clinics in the greater Copenhagen area. The clinics all belong to a public hospital corporation established one year before study start by a merger of three counties. Two clinics (UN1 and UN2) are situated in large university hospitals, and one clinic (CH1) is situated in a big regional hospital. The clinics have between 100 (CH1) and 420 (UN2) employees, approximately 75% of whom are health professionals (nurses, doctors, therapists etc) the rest are either technicians or clerks. The clinics had between 1.000 (in CH1) and 3-4.000 (UN1 and UN2) new patient referrals and 15.000 (in CH1) – 90.000 (in UN2) patient encounters annually.

Patients are referred to an oncology clinic from other hospital clinics with a diagnosis of cancer. Close to 100% of patients are treated according to a treatment protocol (either a standard treatment protocol (75-80 % of the patients) or a research protocol (20-25% of the patients). Most of the clinical encounters take place in combined outpatient and day-clinics. Patients are first seen by a physician either for planning or monitoring of treatment or due to deviations from a planned pathway. Nurses provide care in relation to the encounters and are responsible for administration of chemotherapy. Patients with severe complications either in relation to the primary disease or to the treatment are taken care of in the bed wards.

All the hospitals use computerized patient administration systems (PAS), computerized provider order entry (CPOE), laboratory information systems (LIS), radiology information systems (RIS) and picture archiving and communication systems (PACS). Further, they all have intranet portals that hold several hundred local and regional guidelines, instructions and procedure descriptions (GIP portal). In UN1 and CH1, an electronic patient record application for physician notes has recently been introduced. The same system is soon to be introduced in UN2. In CH1, a medication order and administration system is in use, although the system cannot handle individually produced drugs like chemotherapy, they still have to be ordered and otherwise registered manually. The IT systems are not integrated, and consequently the health professionals have to apply several log-ons and passwords on a daily basis to access the various systems. The hospital cooperation's IT-unit has plans for further consolidation and integration of the IT systems in the region to support cooperation and information integration.

2.2 Data collection and analysis

The main part of the study was carried out in the combined outpatient and day-clinics, as the vast majority of patient encounters take place here. A health professional: a registered nurse, junior house officer or senior consultant was shadowed for 2-6 hours

during daytime of a normal working day. Below the general term “clinician” is used when referring to health professionals who take care of patients. The researchers kept a structured log on when clinical guidance were requested by any clinician, when or whether a CPG was used, or whether other kinds of guidance were applied. Beside the log the researcher kept a diary of the observations. Examples of guiding artifacts were sampled during the observations. Observation notes and interviews were transcribed immediately after the observations and a preliminary analysis were made. The preliminary analysis was presented at staff meetings at the clinics in UN1 and UN2 (CH1 was withdrawn from further participation in the study after the observation study due to a change of management). Afterwards, workshops with 5 clinicians (physicians and nurses) were held in both UN1 and UN2. A brief summary of the preliminary results as well as a prototype of a CPG based declarative workflow model [38] were presented to initiate discussions of how IT could be applied to provide guidance in clinical practice. The aim of the workshops was to identify the clinicians’ demands for guidance in clinical practice.

The workshops and interviews were taped and immediately transcribed. Analysis of the material was divided into two parts: the observations study, ad-hoc interviews and collected artifacts were analyzed together as they all provided information on present practice. The workshops were subsequently analyzed focusing on requests for future clinical guidance. The analysis of both data sets was carried out applying a grounded theory approach [39]. This included familiarization with material, identification of keys issues, indexing of data, charting and mapping and interpretation [40]. A single researcher applying manual coding performed the analysis. Validity of categorizations was ensured by (a) critically examining and re-examining analytical decisions, making changes when analysis of subsequent data sets challenged past coding decisions; (b) by presenting and discussing the preliminary results of the analysis of present practice in the staff meetings and workshops with clinicians from two of the observed clinics to refine the categorization; and (c) validation of final results by two clinicians from two of the participating clinics.

3 Research findings

As observers we were frequently met with comments like “*You are wasting your time, we do not use guidelines*” or “*You will not see much, as we are not using the guideline portal*”. In fact it was true, we did not observe any comprehensive use of the Guideline-Instructions-and-Procedure (GIP) portal or of any other kind of textual CPGs. We only observed a few instances during which these types of guidance were used either by novices or in connection with treatment activities outside the oncology specialty. When questioned about the knowledge management facilities in the GIP-portal, junior doctors revealed ignorance of the search facilities. Those most commonly using the GIP portal were newly appointed junior doctors, who printed out a set of selected local CPGs to hold in his or her white coat pocket until decomposition of the paper.

Use of the GIP portal was not deeply rooted in the clinical culture; we never observed a senior asking a junior who were requesting guidance whether he or she had tried to look up the question of doubt in the portal. In fact, we observed several cases where factual matters like “*What are the common side effects to this kind of chemotherapy?*” and “*How long time is this cure scheduled for?*” were discussed but not being checked in any CPG.

It was obvious that the health professionals strived to achieve a smooth and efficient flow both in their own work and in the individual patient’s pathway, therefore they

pursued to avoid interruptions, as they inevitably would cause delays. Consulting the GIP was perceived as – and in fact observed as – time consuming and thus causing delays. However, we observed an extensive use of pre-printed forms and standard order sets.

3.1 Deployment of clinical practice guidelines in clinical practice

The textual CPG documents, such as treatment and research protocols, and documents in the GIP portal were presented to us in all three clinics. Protocols are a specific type of CPGs originally developed as a formal description of a scientific clinical study including a standardized patient pathway for a specific disease. Within oncology, a tradition has developed to remove research specific parts of research protocols when the study is over and the protocols are passed on as standard treatment protocols. A protocol holds 20 - 100 pages (research protocols being the most comprehensive), each protocol describes in detail how to carry out and monitor a specific chemotherapy cure for a specific disease. The protocols are usually applied by several clinics and may be national or even multinational. In the observed clinics, approximately 50 - 110 protocols were applied at any one time. Although nearly all patients in the clinics were treated according to a protocol, we only observed a few cases where a question of doubt was checked in a protocol.

However, we observed a wide use of pre-printed paper forms and standard order sets. We propose to refer to these forms and order sets as second order guiding artifacts as they were transformed from a protocol or textual CPG (primary guiding artifacts) into another format according to a standard operating procedure. The clinicians did, however, not think of them as CPGs, although they in fact were *systematically developed artifacts to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*, thus fulfilling the definition by Field and Lohr [9].

3.2 Examples of second order guiding artifacts

All the clinics had drawers and cabinets filled with a wide number of what we refer to as second order guiding artifacts. Each form had its own characteristic layout. Similar forms were found in all the clinics. Standard order sets were also comprehensively applied either in the form of preprinted forms or as an integrated part of a CPOE system.

A frequently used second order guiding artifact in all the clinics was the ‘treatment and examination’ form (see **Fig. 1**). The form presented a standard patient pathway according to a specific protocol. The transformation from protocol was based on a standard template consisting of a grid with column heads labeled with treatment day-numbers and rows representing activities organized according to categories. In addition to the grid, the forms may hold other kinds of guidance like decision algorithms for medication and reminders on appropriate care.

The ‘treatment and examination’ form served as guidance for the activity: ‘overview of the patients pathway’, it was an embedded part of the work when ordering and documenting process progress, it was present at the point of care as the form was following the patient and it served as a coordination tool providing an overview and status of the patient’s pathway to all involved actors.

Department X Treatment and examination schedule
Protocol Z
Disease Y

NAME
ID

Signed by consultant 

Height: Weight: Surface m²:

Year Date:											
Treatment day No.:	0	1	8	15	22	43	57	64	85	106	120
Series No.:	Series 1				Series 2	Series 3		Series 4	Series 5	Series 6	
Inf. Docetaxel standard		O			O	O		O	O	O	
Obs. Pre-medication*											
Weight and surface	O				O	O		O	O	O	
BP. and pulse rate	O				O	O		O	O	O	
Performance status	O				O	O		O	O	O	
Physical examination	O				O	O		O	O	O	
Neurological assessment	O				O	O		O	O	O	
Patient complaints/side effects	O				O	O		O	O	O	
Hb. Leucocytes + diff.	O		O	O	O	O		O	O	O	
Thrombocytes	O				O	O		O	O	O	
K, Na, creatinine	O				O	O		O	O	O	
Bilirubin, ASAT,ALAT	O				O	O		O	O	O	
LDH, Serum α phosphatase	O				O	O		O	O	O	
Calcium-ion	O				O	O		O	O	O	
CT scan of thorax and upper abdomen	O						O				O
X-ray, thorax	O										
ECG	O										

Calculation table	
Surface (m ²)	Milligrams
1.45 - 1.64	120 mg
1.65 - 1.84	130mg
≥ 1.85	140mg

On the treatment day: Hb ≥ 5.6 mmol/l, leucocytes ≥ 3.0 or neutrophils ≥ 1.5 x 10⁹/l, Thrombocytes ≥ 100 x 10⁹/l. If not, then postpone until the criteria is fulfilled

Treatment time:

Stop treatment after 3 series if PR is not achieved. IF PR then all 6 series are dispensed

Pre- medication: Tablet Prednisolon 50mg 24 h, 12 h and 1 hour before Taxotere and 12 h and 24 h after Taxotere


Dosage reduction and modification - look at the back site

Fig. 1. Example of a ‘treatment and examination’ form - in everyday speech called a ‘noughts and crosses’ form as “O” indicates that an activity have to be carried out, a “/” in the “O” indicates that the activity has been ordered/booked, and a full “X” indicates that the activity has been carried out. Further, this form holds a simple decision algorithm on dosage calculation and reminders on treatment time as well as a standard order set for pre-medication (the form is translated by the author).

Another commonly applied second order guiding artifact was the ‘ordering’ form (see **Fig. 2**) The ‘ordering’ form was either constructed as a general form to be used in relation to all protocols or as a specific form with preprinted orders for a specific protocol. The ‘ordering’ form was transformed from the local guideline on chemotherapy ordering, preparation and administration. In case of specific forms they were based both on the CPG for ordering, preparation and administration of chemotherapy and on a specific treatment protocol. The form was used in every incident of chemotherapy treatment i.e. it reflected the work that had to be done, when the activity ‘chemotherapy’ was instantiated (the activity was represented by an “O” in the ‘treatment and examination’ form). Basic information about the patient as well as the latest laboratory results could be registered in the form.

Based on the presented information and the patient history, the physician calculated the individual dosage of chemotherapy, ordered it on the form and signed it. Then the form was transferred to the pharmacy for preparation of the actual chemotherapeutic drug. In one clinic this was done by transforming the document into a PDF and sending it by mail, as the pharmacy was situated 500 meters away. In the two other clinics, a nurse carried the form over to the pharmacist a few rooms away. When the preparation was ready the pharmacist validated the preparation and signed the form. Finally, the nurses (two in every case) who administer the chemotherapy used the form for checking information on chemotherapy dosage and patient data before they finally signed off the administration.

The ‘ordering’ form served as guidance for the activity ordering, it was embedded in the work practice as it contained all relevant information and all documentation in relation to ordering and administering chemotherapy, it was present at the point of care as it followed the process and it served as a coordination tool indicating workflow progress by its physical presence. Further, it served as a legal document; hence it carried the prescription from the physician to the pharmacist. The pharmacists are paying close attention to this securing a local copy in the pharmacy.

Department xx				Chemotherapy	
Patient		306		Year: No:	
Diagnosis				Heigth: Weight: Surface (m ²):	
Cytostatics	Date(d/m)				
	Signature : Doctor				
	Pharmacist				
	Nurse				
Adverse effects	Performance status (0-4):				
	Infection:				
	Bleeding:				
	Nausea/vomit:				
	Neurologic:				
	Cardiac:				
	Loss of hair:				
	Other:				
Tumor size	Tumor 1:				
	Tumor 2:				
	Tumor 3:				
	Response status (CR,PR,NC,PD):				
	Measurable parameter				
Lab. results	Hb (mmol/l):				
	Leukocytes (x 10 ⁹ /l):				
	Granulocytes (x 10 ⁹ /l):				
	Thrombocytes (x 10 ⁹ /l):				
	S-creatinine (mmol/l):				
	EDTA-clearence (ml/min):				
	Markers:				
Remarks:					

Chemotherapy

Fig. 2. Example of an ‘ordering’ form allowing for documentation of the most relevant clinical information in relation to chemotherapy (the form has been translated by the author).

We observed several other examples of second order guiding artifacts combining systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstance and a documentation form. Several professions in the clinical practice apply the two forms mentioned above, while other forms are mono-professional. A commonly applied form was the dosage modification table that was developed for every deployed protocol. The ‘dosage modification’ forms served as decision support for physicians in relation to dosage

modifications based on information on patient history of adverse effects and/or abnormal blood test findings. Another commonly applied form was the 'administration and monitoring' form that supported nurses' activities while administering chemotherapy to a patient.

Further standardized order sets were commonly used, both in paper based ordering systems, but especially when deploying CPOE systems in the ordering process. Such order sets were effortlessly and frequently applied and it was clear that the clinicians did not even regard order sets as guidance, although they in fact only served as guidance, as they had to be confirmed – and could be altered if desired – when applied for a specific patient. Standard order sets were mainly used in relation to ordering of medicine and laboratory tests. The standard order sets concurrently served as guidance for ordering activities, they were profoundly embedded in the work providing the relevant information and concurrently providing documentation (if accepted), they were present when ordering was carried out and served as coordination tools in the relation between the orderer and the provider.

3.3 Application of second order guiding artifacts in clinical practice

The second order guiding artifacts provided guidance for decision-making and for planning of activities. The second order guiding artifacts represent a recommended standard set of activities as can be seen in the left column of the 'treatment and examination' form in Fig. 1 and in the upper third part of the 'ordering' form in Fig. 2. When a 'treatment and examination' plan was instantiated for a concrete patient, the immediate situated activities mirrored the activities in the form. However as time passed, the execution differed from the original plan. Deviations from the standard plans were prominent due to adverse effects or due to shortness of resources. On several occasions we observed that when a patient was found to have a leukocyte count below the threshold for chemotherapy administration, treatment was postponed and new laboratory tests ordered. This entailed that the whole pathway was postponed. Shortage of staff and other essential resources was also frequently causing alterations of plans. A limited number of medication pumps in action, for instance, meant that patients who were dependent on a pump for treatment had to wait until a pump was vacant. The result being that the patient's subsequent treatment sessions as well as those of other patients (who also were reliant on a pump) had to be rescheduled. The longer the time frame for a plan, the more alterations occurred during instantiation. We observed that the dates in the 'treatment and examination' forms were not documented until ordering was made, and even then rescheduling implying inserting new dates in the form frequently occurred. The CPG based recommendations had an increasing level of certainty from just constituting advice on how to act, via an actual order, to a request for a specific activity to the dedicated provider that might include booking of an appointment and finally the actual execution of the activity. These levels are reflected in the 'treatment and examination' form with different markings (as explained in the legend at Fig. 1). Nurses and secretaries were observed to use a good bit of their work time on rescheduling patient pathways after adjustments. The rescheduling and/or execution was subsequently documented on the 'treatment and examination' form.

When the second order guiding artifacts were applied as support for decision-making it was apparent (see for example the calculation table in Fig. 1) that clinical decision-making is reliant upon access to patient data. For some of the most commonly applied types of

patient data, such as laboratory results, there was room for a manual transfer of data in many of the forms (as can be seen in Fig. 2). However, it was observed that data seldom were transferred from the original source to the second order guiding artifacts. A nurse commented on this observation: “*we don’t do it as it is double work, and it includes a risk of introducing mistakes due to errors in the transcription*”. Instead, laboratory results were printed and placed together with the ‘ordering’ form.

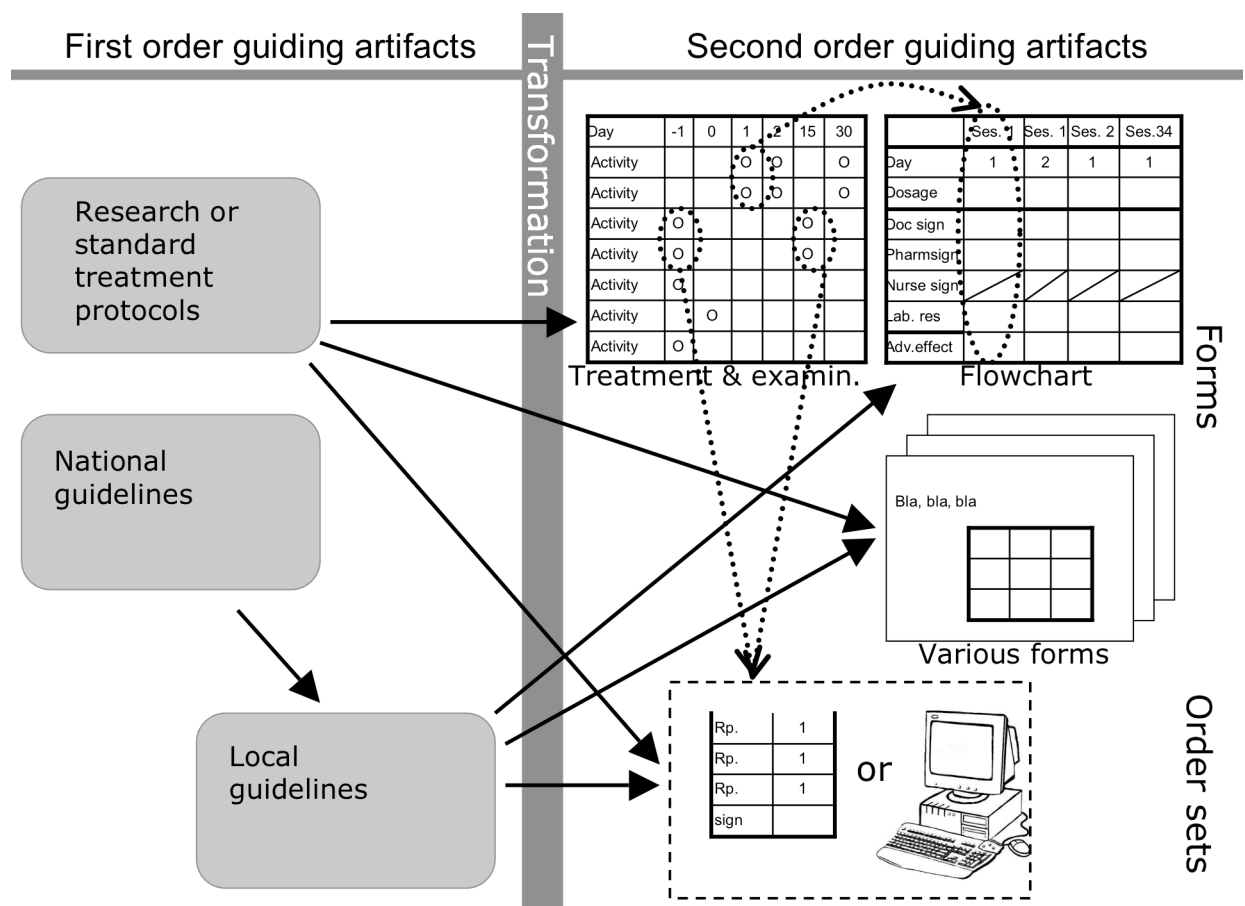
For the majority of patients who were treated according to a protocol, the second order guiding artifacts served as the main artifacts for coordination and documentation, as appears from Fig. 3. In some instances, two or more second order guiding artifacts were applied concurrently, for example physicians used both the ‘treatment and examination’ form and the ‘ordering form’ in an outpatient consultation, while the nurse who administered chemotherapy used both the ‘ordering’ form and the ‘administration and monitoring’ form. The clinicians were concurrently involved in several activities regarding a number of patients, juggling back and forth between them and the appertaining forms. The ephemeral work also included frequent rescheduling of the day program for both patients and clinicians.



Fig. 3 Table with ‘administration and monitoring’ form and preparation of chemotherapeutic drugs ready for administration. In the trays there are packages of forms for patients scheduled for treatment in the near future.

3.4 The transformation from CPG/protocol to second order guiding artifact

For an overview of the transformation from first order guiding artifacts (textual CPGs and protocols) to some of the most commonly applied second order artifacts, see Fig. 4. The transformation from first order to second order guiding artifacts was done according to a standard operating procedure. The task was carried out by nurses in the clinical research units at UN1 and UN2 and by a project nurse in CH1. This has traditionally been so, because each clinic was responsible for printing forms deployed in the clinic. The nurses responsible for the transformation all acknowledged that it would be possible and might even be desirable to share second order guiding artifacts between the clinics. Hence, most of the first order guiding artifacts were shared and the clinics were cooperating on coordination and standardization of clinical work. Further, there was some exchange of patients and employees between the clinics. Slight differences in the second order artifacts were however observed, reflecting local evolution but also differences in organization of work and physical layout of the work place. A standard protocol was transformed to 7-10 forms; for a research protocol there were an additional 10-12 forms. During the transformation process the project nurse consulted relevant actors for clarification of the configuration of the form.



examination' form may be an order managed in an order set or a session of chemotherapy in an 'ordering' form.

The transformation of standard order sets varied depending on whether the order set was to be integrated in a CPOE system or whether it was paper based. In general, the paper-based standard orders followed the above described transformation process. The IT based standard orders were part of the configuration of CPOE.

In the transformation of CPGs and protocols to second order guiding artifacts, a comprehensive toolbox of typographical and other physical features was applied to support overview. Each second order guiding artifact had its distinct physical features that made it easily recognizable in a busy work environment, for instance in one clinic the 'ordering' form was always printed on pink paper. In each clinic there was a standardized relation between second order guiding artifacts and activities, thus the clinicians were able to identify the relevant artifacts for a specific activity at a glance.

3.5 Prominent functionality and features of second order guiding artifacts

The analysis of the observation study and the second order guiding artifacts made it obvious that the various second order guiding artifacts share several characteristics, beside being locally transformed they are activity specific, present at the point of care, embedded in the work practice and serve as coordination tools. The second order guiding artifacts served as the main source of information in relation to many activities, as illustrated in Fig. 3.

Activity specificity When transforming a CPG or protocol to a form, the guidance that in the first order guiding artifact was present in various parts of the comprehensive text was chopped into activity specific bits. The guidance that was relevant for a specific activity was then assembled in the second order guiding artifact. The definition of activities to be supported by a second order guiding artifact has evolved over time and the continuous evolution is decided by the transforming nurse in close cooperation with the affected clinicians. The clinics in our study shared the majority of activity types although a steady evolution was going on, with development of new kinds of second order guiding artifacts. New second order guiding artifacts were, however, quickly disseminated due to close cooperation between the clinics. Examples of activities that were supported by a second order guiding artifact are: ordering of chemotherapy, planning of a patient pathway, reporting of side effects and administration of chemotherapy. The standard order sets were specific for well-defined activities like ordering of anti-emetic therapy in relation to chemotherapy or laboratory tests to monitor potential adverse effects of chemotherapy

Present at the point of care. The second order guiding artifacts were constructed in a format that was suitable to be present at the point of care. Most of the forms were restricted to one sheet of paper. The forms were easily portable and could thus easily be moved around between the physical settings where care took place. The 'ordering' form for instance was moved around between the actors who were active in the ordering-preparation-administration process. The standard order sets were closely integrated into the ordering tools either on paper or computerized; thus always present at the point of care.

Embedded in the work practice. The forms were designed to provide both the relevant guidance and most of the relevant information in relation to a specific activity and it often served as a template for documentation (as can be seen in Fig. 2). This implied a smooth

work process as the clinicians did not have to switch between sources of information and thereby discontinue work to find guidance, relevant information or to document data.

Most of the forms had room for presentation of relevant existing data, like laboratory results, the functionality was, however, as mentioned not widely used. Further, the forms served as documentation templates providing room for specific data to be registered (as can be seen in **Fig. 1** and **Fig. 2**). The standardized format implied a highly standardized documentation. The paper forms, however, now and then caused a conflict; should a note be registered in the record? - Where there would be little chance that clinicians later in the present process would find it, or should it be registered in the form? - With the chance that it would be missed in connection with subsequent treatment sessions, or should it be registered in both places? - Giving rise to redundancy of information, the forms had room for patient identification labels and the computerized order-sets were automatically updated with patient data, avoiding this kind of information to be reiterated.

The standard order sets were profoundly integrated in the ordering process easing the clinical work as all relevant information on a standard order was already present and just had to be linked to the patient

Coordination mechanism. Last but not least, the second order guiding artifacts served as a coordination mechanism. They did so in two ways: first by standardizing work secondly by serving as a messenger carrying information from one actor to another. Standardization of clinical work is an aim for CPGs and protocols. However, in the second order guiding artifacts the standardization was brought one step further as they were providing very specific and detailed information on what to do and how to do it. The messenger function was prominent for some of the mobile second order artifacts like the 'ordering' form or standard order sets that served as a token moving responsibility from one actor to the next.

Some of the second order guiding artifacts served other purposes; the 'ordering' form served as a prescription in the interaction between the physician and the pharmacist. It was also frequent for the forms to hold record information that is encompassed by legislation. The legal perspective put a range of demands on the handling and archiving of the forms.

The guidance both in forms and order sets was presented in a standardized format, thus easy to interpret at a glance for the professional practitioner. The second order guiding artifacts were observed to support the smooth execution of clinical work as they were activity specific, present at the point of care, embedded in the work practice and supporting coordination thereby granting space for the clinicians to focus on clinical tasks.

3.6 Analysis of the clinicians' requests for clinical guidance in practice

The preliminary results from the observation study and a prototype of a declarative workflow engine mimicking the functionality of the 'ordering' form [41] were presented at workshops with nurses and physicians at UN1 and UN2. The themes discussed in the two workshops were remarkably similar: In both cases, the participants took their starting point in the present problems with a patchwork of non-integrated clinical IT systems, demanding frequent log-ons and reiteration of contextual information. The clinicians indicated that they felt that the present clinical IT systems were more of an inconvenience than a tool. The fact that 15-20 minutes were allocated to each patient in the out-patient clinics made the clinicians focus on artifacts that would support smooth work processes, not demanding any additional time consumption. The participants in the workshops, however, stated spontaneously that they were eager to have some kind of IT based clinical

guidance in daily work practice. Although it was also stated as a prerequisite that it should be integrated with the existing clinical IT systems, thus not requiring any new log-ons or re-typing of existing data.

The clinicians stated that they could not see the advantage of IT based guidance of clinical practice if it was to be provided as yet another stand-alone application. It was also emphasized that clinical decisions are made based on existing data like laboratory results, combined with the findings in the actual encounter, thus easy access to sources of relevant patient data was an essential demand. They expected to be able to use the same systems in both clinics; hence at present they shared the majority of treatment and research protocols as well as many of the other CPGs. It was mentioned that a shared system could even make it easier to exchange patients, as was sometimes done to optimize exploitation of resources.

The clinicians spontaneously proposed several types of IT based guidance that they were eager to have: some kind of **overview** comparing the planned and the accomplished patient pathway, like they have today in the ‘treatment and examination’ form. Although they would like it to be integrated into a CPOE with facilities for ordering and rescheduling, it should also provide an overview of the status of planned activities, so that it would be possible to see if an examination had been carried out and if there were any new results. The clinicians would also like to have some kind of **automated ordering** when subsequent steps in a standard patient pathway were instantiated. Concurrently, there was a demand for being able to **re-model** individual patient pathways on the fly, adding or removing activities from a patient’s pathway. Finally, they would like to have some kind of **alert or reminder** when specific activities like re-assessment of patient status were due to occur. This is currently a task that is frequently overlooked as the timing of it is relative (i.e. it has to be carried out after N series of chemotherapy) and it may be postponed to the next contact with a specialist consultant.

The clinicians further had several requests as to the features of IT-based clinical guidance. First of all it should be easily **accessible** without any impediments in the clinical work situation. This implied, according to the clinicians, that guidance should be speedy and punctual not requiring additional log-ons or re-typing of contextual information. The guidance should be **specific and relevant**, just providing guidance for a specific work activity, presented together with relevant patient data. However, it should be easy simultaneously to obtain an overview of the accomplished and intended patient pathway. Some of the clinicians stated that they would find it beneficiary to have a process support tool merely documenting deviations from a standard pathway, thus not having to make any detailed registration when an individual patient was proceeding according to the standard pathway. The clinicians found it of major importance that future IT tools should **support the mobility and ephemerality** of health professionals as do the existing paper based guiding artifacts. Especially the nurses requested support for this as they move around continuously and frequently switch focus back and forth in between patients. The clinicians stated that it was important to have **information intensive displays**, as they would prefer to avoid switching between windows. As one of the physicians expressed it: *“We are professionals, and we are used to capture a lot of information at a glance.”*

4 Discussion

CPGs are published with the aim of improving clinical practice [9]. In our study we found that although most of the patients in the oncology clinics are treated according to a

CPG in the form of a protocol, the comprehensive textual CPGs were seldom applied in clinical practice. Instead we found widespread application of what we have conceptualized as second order guiding artifacts. Second order guiding artifacts circumvent the inconveniences of applying CPGs, such as troublesome retrieval requiring interruption of work, and exhaustive knowledge presentation beyond specific needs. The second order guiding artifacts were observed to serve as efficient process support tools.

It is well known that even though electronic health records are implemented there is a persistence of paper based work practice [42]. We found that paper based work-arounds also exist on a wide scale for document based knowledge systems. The persistence of paper based work practice is not just a question of conservatism but just as much an issue of pragmatism. This has to be taken into account when designing computerized CPG systems if the full advantage of going electronic is to be achieved.

Marc Berg argues that healthcare is unfit for business process management tools because: *“In health care, however, the ‘core business process’ consists of highly knowledge-intensive, professional work, typified by a complexity that defies the predictability and standardization required for simple reengineering”*[43]. This viewpoint, however, is contradicted by the fact that we found a substantial number of standardized second order guiding artifacts applied in clinical practice. An important issue, however, is that the majority of the applied second order guiding artifacts provide guidance for specific activities where the clinicians themselves have to define relations between activities when relevant. Further, our observations are made within oncology that has a long tradition for highly standardized patient care.

We found that the clinicians were eager to have some kind of computerized guidance integrated into other clinical IT systems to support clinical practice. We will argue that the current comprehensive use of paper forms is due to the impoverished design of IT support within hospitals. Therefore, it is relevant to seek inspiration in the functionality and features of the extensively applied second order guiding artifacts.

4.1 Guidance as a resource for planning

The clinicians in our study viewed clinical guidance merely as a resource rather than as a determining factor when planning for a specific patient. Clinicians deviated from the recommendations whenever they found it appropriate, including, altering and excluding activities based on clinical judgment of the patient and the context. Some protocols have very long treatment periods that may exceed a year. Patient plans, however, are not instantiated for such long periods. Planning periods seldom go beyond the next series of chemotherapy. Further patient plans were frequently altered after instantiation either due to patient related reasons such as severe side effects or due to resource problems in the clinic. Alterations of patient plans may have an impact not only on the specific patient’s clinical pathway, but also on consumption of clinical resources. The result being that rescheduling of a plan may not only have implications for the patient in case, but also for other patients as they all are reliant on the same resources.

Timeliness is an important issue in healthcare [44]. However, the demands on timing differ substantially. When an oncology protocol states that specific laboratory test have to be taken on day 8 after chemotherapy, this may in practice be interpreted as a working day (excluding weekends and holidays) as close to day 8 as feasible. This might not even be stated in the order to the laboratory, but the patient is instructed to show up at the laboratory within a time period. In relation to other tasks, such as pre-hydration before

administration of chemotherapy, the time window is restricted within an hour. Knowledge about this is part of the professional training of the clinicians and is seldom explicit in CPGs – unless it deviates from the usual procedure within the field. The clinicians are experienced in juggling around with tacit knowledge and ambiguities. However, if computerized tools are to be applied these ambiguities have to be dealt with and tacit knowledge has to be made explicit [45].

The clinicians stated that they would like to have automated ordering when a plan is instantiated and/or postponed. For computerization of CPGs and standard patient pathways, processes have to be presented in a declarative manner [46] and integration to CPOE must be established. Therefore, it is essential that flow logic is separated from the application code [32] and a shared standard reference terminology and semantic for CPGs and clinical IT are established [47].

4.2 Guidance embedded in work practice

The clinicians in our study requested that computerized clinical guidance be provided in a way that is easily accessible and support clinical work practice. The second order guiding artifacts fulfill these requests that are well in line with reported recommendations on guidance to be timely and relevant [30, 48, 49]. The present knowledge management systems such as the GIP-portal do not honor these requests. The clinicians perceived the system as an obstacle, as application interrupted work because it was necessary to enter a password and problem information in order to search for relevant knowledge. Further, most of the published CPGs are comprehensive documents providing extensive knowledge beyond the specific needs.

Clinical decisions and plans are made based on patient information. Therefore, it is important to the clinicians to have easy access to relevant information in the work situation, not having to dig it up in various sources. Most of the currently applied clinical computer systems are task based, mimicking paper records, requiring new log-on and context information for every task, implying a much more cumbersome work process than the paper based original. Further, experienced clinicians are not rational decision makers, examining existing clinical data in a predefined order. Instead, they search for data patterns that in turn instantiate professional scripts [50].

Documentation templates serve both as guidance and as facilitators of efficient work processes. Preprinted forms put demands on specific data to be obtained and specific operations to be made. Concurrently, the form makes it easy to document the data in the work process. Applying the second order artifacts for documentation of clinical data means that the forms must be covered by legislation on patient data. The current practice of documentation both in patient medical records, the chart and second order guiding artifacts implies ambiguities and redundancies in data registration.

The findings in our study indicate that knowledge presentation should be accomplished in a way that will not require interruptions in the clinician's workflow. This implies that CPG computerization should not include only presentation of guidance, but also presentation of other types of information necessary for the recommended activity. Such presentation of information, however, may be achieved in a pragmatic way ensuring presentation of relevant data rather than a full fledged integration [51].

4.3 Activity specific guidance

Activities are outlined work processes with a specific aim, although not well defined entities; they were, however, found to be similar in all the observed clinics reflecting shared concepts. Activities can be realized through chains of actions, which are carried out through operations [33]. The second order guiding artifacts were found to provide guidance for all levels. From guidance on the superior planning of a patient pathway as in the ‘treatment and examination’ forms to guidance on specific activities and actions as in ‘ordering’ forms and ‘administration and monitoring’ forms and to very detailed guidance on operations as in standard order set’s.

The second order guiding artifacts do not just provide activity specific guidance, but also activity specific information and documentation templates, entailing that the clinicians only have to use one or two second order guiding artifacts in the work process.

Computerization of activity specific guidance can be achieved in the most basic form by computerization of second order guiding artifacts or in more advanced forms based on monitoring of the clinical workflow matching it to the relevant CPG [52]. Further, in computerized solution activity specific information from several sources such as laboratory system and CPOE should be presented concurrently.

4.4 Guidance at the point of care

Paper forms are easily portable and the standard order sets are integrated in the ordering systems whether paper based or a CPOE. This implies that the guidance is present where the clinical work takes place. Thus, problems with unawareness of relevant guidance are bypassed and the clinicians do not have to interrupt work to seek for relevant guidance.

Clinical work is highly contingent and interruption driven [33, 53]. We observed that especially the nurses went to and fro and frequently changed focus in between patients as well as referring responsibilities between each other.

To be able to provide computerized guidance at the point of care, a computer artifact has to be present at the point of care. This can be achieved either by portable devices [54] or by stationary computers at all work places and activity aware applications [55] or by a combination of the two concepts. Further, computerized clinical guidance should support contingent collaborative work practice where responsibilities are moved around between actors.

4.5 Guidance and coordination of work

A major issue for CPGs is work practice standardization based on best existing knowledge [56, 57], thereby mediating coordination as standardization has proven a very powerful method for work coordination[58]. Therefore, CPG computerization can serve as a vehicle for computerized clinical coordination. Most of the existing clinical IT systems are designed for storing and presentation of data, not really supporting the highly collaborative work in hospitals [59].

The second order guiding artifacts were observed to serve as coordination tools in the cooperation between clinicians, although coordination is still to a large degree accomplished by oral communication. The second order guiding artifacts, however, were

observed to have the benefit of mediating coordination between clinicians across locations and shifts.

CPG computerization implies the potential of providing transparency and overview of the process to all stakeholders and not just to those close to a form. Further, this may lead to improved coordination, as it will be possible for subsequent participants to take early action based on registered actions. This is already the case for the computerized standard order sets that have eliminated the need for transport of order forms and for frequent contacts between orderer and producer to clarify status of the order.

4.6 Transforming CPGs to guidance applicable in practice

We found that a wide array of graphical features was applied in the second order guiding artifacts to ease usability. Colors, fonts and various tables supported pattern recognition ensuing overview in practice [60]. Most of the graphical features were applied consistently by all the observed clinics.

In our study, transformation from primary to second order guiding artifacts was executed in the local clinical research units. The nurses responsible for the transformations and the clinicians in the workshops acknowledged that closer cooperation on transformation would be desirable, as it could support collaboration among the clinics. Shared guiding artifacts will put further demands on work practice standardization.

In the transformation process, guidance was fine-tuned to correspond with local resources. Thus, found minor local variations in the presentation of guidance were found. A need for local adaptation of non-local CPGs may always be expected due to variations in organization of work and access to resources [61]. When guidance is computerized there is also a need for integration into local IT systems. The demand for local adaptation and mapping to local IT-systems will grow with higher levels of automation of execution [21].

4.7 Limitations

Limitations of this study should be taken into consideration. Since this was a qualitative study of the use of guidance in clinical practice, we do not have data to support any deviations from protocols or the quantitative benefits of using second order guiding artifacts.

The second order guiding artifacts have evolved over decades to support efficient clinical work practice and they are profoundly integrated in practice, so it would not be possible to examine how practice functions without them. Nor is it possible to make a substantial quantitative examination of CPG application, as experienced professionals will not seek guidance for activities that they are familiar with. This is, however, also the Achilles' heel of the present knowledge management systems; experienced clinicians do not seek guidance due to unawareness of new or altered recommendations [14].

In our observations it was obvious that the currently applied paper-based second order guiding artifacts have some substantial drawbacks: they imply a risk of missing information, as they are only present in one place, and they are not extensively integrated into each other or to any source of patient information. The limited format of paper forms and standard order sets entailed prioritization of operational guidance, leaving no room for comprehensive explanations. It should, however, be possible to address these flaws in an

intelligently designed computerized CPG system capable of substituting the larger part of the functionality and features of the second order guiding artifacts in a way that efficiently supports clinician work practice.

4.8 Designing computerized CPG systems

In line with other observations, we found that clinical work is highly collaborative, mobile and ephemeral [62-64]. Thus, it is a challenge to develop computerized CPG systems to support it. We argue that a precondition for success is to make clinical work the starting point rather than the traditional technology perspective [34].

In most reports on CPG computerization, executions are accomplished as workflow systems, developed as enabling technologies for the accountability of the organization. Even though workflow engines can be viewed from a broader perspective than just being a system of accountability [33], workflow engines cannot solely reflect the comprehensive functionality that we found in the applied second order guiding artifacts. Dynamic declarative workflow engines have to be a substantial part of computerized CPGs, but other aspects such as local adaptation, activity specific guidance, presentation at the point of care and concurrent access to presentation and documentation of relevant patient data have to be taken into account when designing computerized CPGs.

Providing situated activity specific guidance is well in line with the CSCW approach; changing focus from a deterministic, reactive, data-sampling and technology-focused approach, to a proactive and assistive technology approach for contingent collaborative work [65]. To be able to do so, a more profound understanding of clinical work practice has to be established and easy accessible computer modalities for hospital environments [55] have to be developed. Our study demonstrates the level of understanding needed to design CPG computerization in a manner that will meet the requests of clinicians and clinical work practice.

Taking into account that potentially many thousand CPGs [66] may be computerized, there is a need for developing standardized methods for design of computerized CPGs. Goud et al [67] have shown that it can be beneficial with multi-actor cooperation in the early stages of CPG and IT development, securing that CPGs are coherent and valid and can be embedded in the IT tools. There is, however, also a substantial need for aligning CPG computerization to clinical practice, so the design will support application.

5 Conclusions

With paper based second order guiding artifacts meeting most of the requests for clinical guidance, why computerize CPGs? The paper based second order guiding artifacts have some major disadvantages; they breed the ground for redundant registration or overlooking of data, they are only accessible in one place and they do not fit well into a computerized environment. Besides, they are only known to have gained widespread application within oncology. Further computerization can help disseminate CPGs and support establishment of efficient updating procedures for frequently altered CPGs [68] and it will be possible to link to sources of thorough accounts of guidance.

IT for clinical guidance should not mimic the presently applied second order guiding artifacts, but it should be able to substitute most of the functionality and features of the

artifacts in a way that fulfill the clinicians' requirements on smooth efficient support for clinical work. A starting point could be application of some of the major characteristics of the second order guiding artifacts in CPG computerization: activity specificity, physical presence and easy accessibility in the work situation, dynamic transformation and presentation designed in close cooperation with the clinicians.

We found that clinicians were eager to have computerized guidance. However, there is a need for establishing a better understanding of the interactions between clinical work, clinical guidance and clinical IT if the aim of providing computerized guidance for "*appropriate health actions for specific clinical circumstances*" [9] is to be fulfilled. This will require further research and extensive cooperation from a wide variety of experts.

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Summary Points

What was known before the study?

- Much effort has been put into the development and publication of clinical practice guidelines (CPGs) to improve the quality of care. It has, however, proven difficult to achieve comprehensive compliance in clinical practice
- Application of computerized CPGs has been shown to improve quality of care
- Many attempts have been made to computerize CPGs in form of workflows. The systems are, however, not widely applied in clinical practice

What the study has added to the body of knowledge

- In an area where the vast majority of patients are treated according to protocols, the comprehensive textual CPGs were not applied in clinical practice, instead numerous activity specific second order guiding artifacts were applied.
- Second order guiding artifacts are characterized by being locally transformed, activity specific, present at the point of care, embedded in the work practice and, supporting coordination of work.
- Clinical work practice has to be taken into account when designing computerized CPGs for use in clinical practice
- Mimicking the functionality and features of second order guiding artifacts could be a feasible starting point for computerization of protocols and CPGs to improve application in clinical practice.

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Participatory Design for computerization of clinical practice guidelines

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Abstract

Clinical practice guidelines (CPGs) are computerized for various reasons, applying many kinds of formalisms. Computerized CPGs have, however, not yet achieved any general application in clinical work practice. We argue that one reason for this is due to the design methods applied for computerization of CPGs. The commonly applied methods for computerization of CPGs do not include requirements from clinical work practice and business strategy. Participatory design (PD) where the users are actively involved in the design process does include these aspects. A review of the literature on PD focusing on issues of relevance for CPG computerization is presented. Additionally, the application of PD for computerization of CPGs is illustrated by two cases. We conclude that PD is a beneficial approach when designing computerized CPGs

1 Computerization of Clinical Practice Guidelines

Information technology is increasingly seen as a contributor to improvements in quality and efficiency in the healthcare sector [1, 2]. However, to achieve these aims, the information technology needs to provide clinical work process support [3]. An obvious way to do this is by computerizing clinical practice guidelines (CPGs).

CPGs are intended to influence the health professional's decisions, their work actions and thereby ultimately the outcome as to the patients [4]. By addressing health professionals, CPGs are encompassing a potential paradox, as professionals by definition have a high level of standardized skills, that allows them considerable control over their own work practice and work related decision-making [5]. This is reflected in the problems of making professionals comply with CPGs [6].

Various stakeholders such as governing bodies, professional societies, administrators and healthcare managers publish CPGs for various reasons and aims. The reasons for CPG publication vary from simple memory support to regulation and control of work [7, 8]. Further, access to and application of relevant CPGs has become a precondition to accreditation [9]. Most aims for CPG publication can be related to business strategic goals such as: safety, effectiveness, patient-centeredness, timeliness, efficiency and equitability [1]. These differences in reasons and aims form a field of potential conflicts that have to be dealt with together with the professional paradox while implementing CPGs in clinical work practice, no matter whether the implementation is supported by physical documents or computerization of CPGs [10].

Due to the difficulties of obtaining extensive compliance with CPGs in clinical practice [6, 11], it is recommended that a multifaceted implementation approach should be taken into account [10]. Computerization of CPGs is an obvious facet in a multifaceted introduction strategy as the healthcare sector currently is experiencing a comprehensive introduction of IT [1, 12]. Thus, CPG computerizations should provide more than just indexing and presentation of CPGs; the computerized CPG should be able to present CPG-based guidance when and where it is relevant in clinical practice. This can be achieved on various levels of automation [13] either in the form of computer interpretable guidelines (CIG) or more advanced as computer executable guidelines (CEG) [14] .

Many attempts have been made to computerize of CPGs [14, 15]. Even though there are significant examples of CPG computerizations that has proven to have a beneficial effect on process outcome [16] as well as on patient outcome [17, 18], computerized CPGs have not gained any wide-scale application in clinical practice. Most of the current CPG computerizations have been made based on an analysis of the intrinsic information in CPG documents, without consideration to the work practice or the business strategy of the context where the computerized CPGs are to be applied [14, 19, 20].

Until recently, most computerized CPGs were made as procedural workflows where all possible actions were pre-defined. This method, however, does not provide room for flexibility and exception handling during execution [19]. Further, computerized guidance relies on thorough monitoring of the clinical processes to provide pertinent guidance [12]. Finally, the organization of clinical work practice may have to be altered due to CPG recommendations. Therefore, it will be beneficial if requirements from both the existing as well as the intended future work practice are taken into account when designing computerized CPGs. This places high demands on the design approach for the design of computerized CPGs. The applied design approach should address both intrinsic CPG issues as well as changes in the socio-technical environment [21, 22]. Taking the socio-technical environment into account implies developing a thorough understanding of the clinical work practice and the business strategic aims in general as well as for the aims behind introduction of computerized CPGs. The socio-technical match play a major role in determining whether an application will turn out to become a success or failure [23]. Given the problems described above with computerization of CPGs, we sat out to explore how a participatory design (PD) approach can contribute to improved application of computerized CPGs in clinical work practice.

PD is a socio-technical design approach that takes its starting point in a thorough examination of current work practice and business strategic aims for the future work practice [24].

Being a socio-technical approach, the basic assumption in PD is that the technical features of a computer system are contemplated as fundamentally interrelated with the work practice and business strategy of the context where the technology is to be applied. In PD, the end-users and other stakeholder are actively involved participants in the design process as work practice specialists. A major issue in the PD approach is to establish a realm of mutual understanding, where IT-designers and participants from the work practice meet on equal terms [24]. The aim of applying a PD approach for the design of computerized CPGs is to disclose not only intrinsic CPG demands through document analysis and model making [25] but additionally to include work practice and business strategic demands by engaging users in the design process. Outside dedicated PD research groups, the non-technical or socio-technical aspects of systems design are often overlooked, although these aspects are of major importance in healthcare [21, 26-30]. Researchers have already shown that PD can be useful for the design of clinical IT systems [30-32]. Therefore, we would expect PD to be a beneficial approach in the design of computerized CPGs.

The objective of this paper is to 1) explore the potential benefits – and disadvantages – of PD as an approach to design of computerized CPGs, and 2) to raise awareness about the impact the design method have on the final solution. However, rather than attempting to comprehensively cover the whole field of PD pertinent to healthcare, we focus on providing details on three aspects of PD: PD as a design philosophy, PD as a toolbox and PD as a way to create a shared realm of understanding among IT-designers and health professionals as these are areas of outmost relevance for the design of computerized CPGs. Finally, the benefits and shortcomings of the PD approach for design of computerized CPGs are discussed.

To illustrate how PD can be applied as a remedy for the challenges described above, we present a focused review of PD literature and two cases of CPG computerizations where a PD approach has been applied. We do not claim to address the entire multitude of challenges in the design of computerized CPGs. Rather, the cases serve as examples to illustrate our points; how PD can be helpful in the design of computerized CPGs, and that the tools and techniques applied have to be accommodated to the design task. Design of computerized CPGs entails not only introduction of new technology, but also implementation of recommendations for alterations in medical practice and may imply changes in the organization of the clinical work. This places high demands on the design as well as the implementation approach.

1 Methodology

The paper consists of an analysis based on theoretical and empirical data drawn from a literature review and two empirical cases, respectively.

A systematic search has been made for scientific papers on 'participatory design' and 'hospital' in the ACM portal. In PubMed, a search was made for the MeSH terms 'participatory design' and 'information system'. Additional searches were made for '(clinical practice) guideline' and 'information system' or 'computer'. The objective was to select peer reviewed English language papers where PD relevant for the design of hospital IT systems were presented and discussed, primarily papers from 1990 and onwards were selected. Google Scholar was used to examine the impact of the papers in form of number of citations. Based on the title and the abstract as well as the impact factor in form of registered citations, papers were selected for further reading.

Key features have been extracted by analysis of the papers based on questions such as: 'what are the key features of PD?' 'What kind of benefits and shortcomings can be expected when applying PD?', 'What are the experiences with application of PD in the healthcare sector?' and 'what can application of PD bring to the design of computerized CPGs?' Extracting these issues from papers has helped us identify key perspectives of relevance for the design of computerized CPGs.

We further present two cases to illustrate some of the potentials of a PD approach for the design of computerized CPGs. The cases show how the philosophy of PD may be practiced and how the tools and techniques help develop a shared realm of understanding in the design team. Finally the findings from the literature review and the experience from the cases are discussed in the discussion chapter.

2 Participatory design

PD has its roots in late nineteen sixties Scandinavia where it was initiated by researchers in cooperation with trade unions as a reaction to computer-automation of work. Initially, the aims of PD was inclusion of democratic values and increased autonomy of the employees in the introduction of new technology [33]. The end-users, who were regarded as specialists in their work field, should therefore be actively included in the design of the information systems they should apply in their work [34]. Since PD was introduced in the late 1960s, it has undergone a development and maturing [29, 35]. PD has evolved to include not only employees, but also managers and other stakeholders and has been used as a framework for large-scale system design and evaluation of information system design in healthcare [29, 36, 37]. There exists

however no single coherent definition of PD, therefore PD is usually described by its principles and practices [35, 38]. The core principle of PD is that people, are actively participating in system design activities where they have power to influence the design solutions [35] [39].

Rather than attempting to comprehensively cover the whole field of PD, we focus on issues of major relevance for computerization of CPGs. We have identified three issues that have dominated the discourse in the PD literature of major relevance to the design of computerized CPGs: (1) the philosophy and politics of design, (2) tools and techniques for the design process and how they can provide a (3) realm for understanding the socio-technical context and the business strategic aims [34, 35].

2.1 The philosophy and politics behind PD

PD can be regarded as an epistemological approach to the design process, where the users are participating as work practice specialists. In PD, a key concern is that users are given a tongue and a direct influence on the design through active participation in the design process [34]. The participants from the field of application can include not only end-users, but also other stakeholders, such as managers and users of process results who can have a major interest in the development of new technology to be applied within the area of work. Actively including users in the design process, not just as observation objects or as potential operators of the solution, but as fully-fledged members of the design team, implies a democratization of the design process with delegation of power to the participants [30, 39]. The philosophy behind the promotion of PD has diversified over the years so that PD is now applied for various non-political reasons, such as a way to improve functionality of the design and to establish ownership of the design solution within an organization implying facilitation of a smooth implementation process [24, 30, 35]. Furthermore, economic concerns are now used as arguments for PD, where efficiency in the design process and in user interaction with the solution are emphasized over empowerment of employees [40].

The PD approach implies that the users are considered active participants in the whole design process from planning and execution to evaluation of the design. This is in contrast to other user-involving design methods like usability engineering [41] and contextual design [42] where the users are regarded more as study objects or provisional team members. The PD approach is well in line with general guidelines for CPG implementation, where active user involvement in the implementation process is recommended as an approach to improve application [43]. Within workplaces, many of the initial claims and arguments put forth by the PD community in the early days have now become integrated parts of work organization and cooperation practices and norms, so that employees are involved in the process when alterations of work-practices are

considered [44]. This is highly relevant in relation to design and implementation of computerized CPGs, as there often is a need for local adaptation of CPG documents based on local clinicians' requirements [45].

2.2 PD as a toolbox

PD is not a predefined method, but an approach that includes a conglomerate of tools and techniques to be applied [24]. The tools and techniques serve as remedies to establish a shared realm of understanding based on knowledge of how the work is carried out, and how it can be carried out in the future [34]. Over the years, PD researchers and practitioners have developed a wide number of tools and techniques that promote efficient exploration of current as well as potential future work practices. A key issue in this is a productive and efficient participant - IT-designer cooperation [30, 46]. Some of the tools and techniques most commonly applied within PD of relevance for CPG computerization are listed in Table I.

Within most PD projects, ethnographic work and design processes are combined [34, 35]. In PD, developing some degree of shared knowledge about current practices constitutes the foundation for designing for the intended future practice. Based on studies of current practice problems can be articulated and solutions sought for. This is especially important in relation to computerization of CPGs as both the CPG in itself and the introduction of new technology can lead to new ways of working.

Prototyping is frequently applied in PD and may range from simple paper mock-ups to full-scale running prototypes [30, 47]. The Prototypes can serve various purposes: they can be serve as a kick starter facilitating user articulation of problems and requirements, they can be used to test different ideas and they can serve as a technique for development as well as for validation of the final solution [48].

Not all tools and techniques are to be applied in any design process. When the design project is initiated, decisions have to be made on which tools and techniques to apply [24]. The selection of tools and techniques should be made in cooperation among users and IT-designers to ensure enlightenment of substantial problem areas within the focus area [30]. Most of the tools and techniques presented in Table I imply some kind of interaction between the IT-designer and the user. The interaction should take place in an unprejudiced environment where both users and IT-designers can contribute openly with their respective disciplinary knowledge [46]. This requires that the users and designers have – or are trained to have – cooperation and communication skills.

PD tools and techniques	Relevance in relation to computerization of CPGs
<i>Document analysis</i>	<i>In addition to analysis of the CPG document in case, this also includes an analysis of instructions for organization of work and standard documents and forms applied in practice</i>
<i>Site visits and observation studies</i>	<i>This provides a firsthand experience with current work practice, and includes observations of the currently applied guiding artifacts and any difficulties in complying with CPGs. Can help overcoming 'say-do' problems</i>
<i>Questionnaire</i>	<i>Can be used to quantify observed problems and can provide support for prioritization of observed problems</i>
<i>Interviews</i>	<i>Can be used to reveal:</i> <ul style="list-style-type: none"> <i>• User perceived problems in current work practice that may hinder CPG compliance and</i> <i>• Frequently occurring exceptions that have to be met while computerizing CPGs</i>
<i>Workshops</i>	<i>Can be used to establish a shared knowledge about:</i> <ul style="list-style-type: none"> <i>• Current practice and the problems it may imply,</i> <i>• The implications of CPG compliance and</i> <i>• Strategy for future work practice</i>
<i>Drawings of 'rich pictures'</i>	<i>Where users draw a rich picture of the current or future work practice, and the applied artifacts. Can help disclose user requirements</i>
<i>Role-playing and simulated environments</i>	<i>Can be used to study specific details through repetitions and it can be used for testing of modifications in mock-ups or prototypes in full-scale environments</i>
<i>Diagnostic mapping</i>	<i>Systematic mapping of CPG compliance problems, their causes, consequences and possible solutions in a diagram that can be used for prioritization of which problems to address in the design.</i>
<i>Mock-ups and prototyping</i>	<i>May include artifacts from simple paper-based mock-ups to full scale running prototypes of computerized CPGs – can be used to:</i> <ul style="list-style-type: none"> <i>• Initiate discussions on requirements,</i> <i>• For testing various design possibilities or</i> <i>• To verify the final solution</i>

Table I An overview of PD tools and techniques relevant to computerization of CPGs, based upon [24, 29, 36, 49, 50]

2.3 PD as a realm for understanding the system context and aims

A basic assumption behind PD is that users have profound knowledge about their work practice, and that IT-designers have knowledge about technological possibilities, and that they are able to share this knowledge and jointly create new knowledge in the design process [34]. The purpose of PD is to establish a mutual learning space where the users learn about the possibilities and constraints of information systems and computers, while the designers learn about the work practice, including the basic assumptions of clinical practice and the business strategic aims. In healthcare, where several professions and medical specialties often have to cooperate on the activities described in a CPG, it is important to establish an efficient cooperation not only among participants and IT-designers, but also among the participants as they may not have a thorough knowledge of what the other health professionals are doing [30, 46]. The mutual learning space constitutes the basis that makes it possible for the users to articulate work problems in a way that can be understood by the IT-designers and thus can serve as requirements for the design. The application of a careful selection of the tools and techniques presented in 2.2 can facilitate the creation of a common understanding among users and among them and the IT-designers. An effective way to support the mutual learning and relation building can be by introducing process facilitators [51].

An important issue that has to be understood and sometimes also negotiated in the design process is the business strategic aims for the operationalization of the CPG recommendation. Detailed decisions have to be made on how the CPG guidance is to be carried out in practice. As mentioned in the introduction, CPGs are introduced by various stakeholders for a wide number of reasons. In the design process, the potential achievements have to be prioritized. Prioritization of efficiency over patient-centeredness or effectiveness will have a profound impact on the design. Thus, it is important to establish a shared realm of understanding for the consequences of the strategic design decisions [30].

3 Designing CPG computerizations with a PD approach

When planning design of computerized CPGs, it is important to understand the various issues in PD and how they influence each other and the design process. The focus in the philosophical perspective entails decisions on whom to involve and how to involve them. Within a complex organization such as a hospital it can be difficult to exactly define who the users are and whose work will be influenced by the introduction of new technology. The choice of tools and techniques influence data collection and have an impact on both participant involvement and on the establishment of a realm of understanding. To illustrate some of the potentials of PD we present two cases, where we have applied a PD approach for the design of computerized CPGs.

3.1.1 Case A: The advanced life support case

Case A: The aim of this project was to computerize the clinical part of the European Resuscitation Councils guideline for Advanced Life Support (ALS) [52] in case of cardiac arrest. The business strategic aim of the computerization was to promote clinicians' adherence to the guideline. The project took place at the Danish Institute for Medical Simulation (DIMS). DIMS is a highly specialized research, development and training unit situated at a large university hospital. The institute is responsible for ALS-training of all health professionals (app. 3000 employees) at the university hospital. In the hospital, app. 300 cases of cardiac arrest occur among hospitalized patients every year. The hospital has established cardiac arrest teams that are comprised of a junior doctor from the cardiology clinic, an anesthesiologist, an anesthetic nurse and two porters. The cardiac arrest teams are ad-hoc teams constituted of those who are on call at any given time.

The philosophy behind the design project: The project was established as a joint venture between the management at DIMS and a research group at the IT University of Copenhagen. The project period was limited to four months, so efficiency in the design process was required. A steering group was established to establish ownership and a broad involvement from DIMS, from clinical practice and from design researchers. A project group was established with four health informatics students, two with an IT-technical background and two with a health professional background. The empirical research took place both at the DIMS premises and at the cardiology department at the university hospital, as DIMS is responsible for the ALS training, and the cardiology department is responsible for the medical treatment in cases of cardiac arrest. In this way, it was possible in an efficient way to involve work practice specialists from the two main stakeholder units. It was part of the business strategic aims that the solution should be an integral part of ALS training at the hospital, to make the users confidential with the solution during their professional training. Due to the democratic design process where decision power was delegated, a new aim was brought forward during the project and an additional strategic decision was made: that the solution should support collection of process data for further clinical research on cardiac arrest and ALS. The active involvement of end-users implied detailed requirements that entailed an extensive focus on the user computer interaction in the stressful working situation during ALS.

The applied tools and techniques: The project started out with a workshop including the ALS trainers at DIMS and the project group, to preliminarily define the area of concern. Due to the logistic and ethic problems of doing observations in real cases, and the fact that two of the project group members were experienced cardiac team members, it was decided only to do observations

in a simulated, but full scale realistic training environment. This additionally allowed for videotaping of the observed sessions. Two full days of ALS training were observed. After the ALS training group interviews were made with the trainees. A questionnaire was given to all doctors in cardiology to quantify the doctors' experience with ALS and their perceived challenges in relation to ALS. Diagnostic maps (see an example in Figure I) were applied for analysis of the data from the observations and the questionnaire. All in all, ten problem areas causing widespread challenges in adhering to the ALS guideline were identified. Against this backdrop, a set of proposals for a solution were developed. The proposals were discussed in workshops at DIMS. Subsequently, a prototype was developed and tested in full-scale simulation. Based on the findings and feedback, this first prototype was further developed in cooperation with the ALS teachers from DIMS to a running prototype version, called CardioData [53]

Monthly meetings were held in the steering group during the design period to make decisions on alterations in scope and aims of the project.

Problem	Causes	Consequences	Ideas for solution
<i>Two-minute intervals for check-up on patient are not observed</i>	<p>4) <i>It is difficult to keep track of time in an urgent situation</i></p> <p>5) <i>The sense of time is lost and time is experienced differently by various team members</i></p> <p>6) <i>There is no master watch present</i></p>	<ul style="list-style-type: none"> • <i>The CPG algorithm is not observed</i> • <i>Inadequate quality of the ALS treatment</i> • <i>Non-application has an impact on patient survival and possible outcome (brain damage)</i> 	<ul style="list-style-type: none"> • <i>Digital "chess watch" in all hospital rooms, able of counting down in two-minute intervals</i> • <i>Ensuring a standing timer role</i> • <i>Integration between watch, computerized CPG solution and defibrillator</i>

Figure I example of a diagnostic map for one problem. In the project, several problems were identified. The numbers in the 'causes' column are sequential numbering of the causes identified in the project, i.e. several problems may be caused by the same causes.

The realm of understanding: Involving actors from the unit responsible for ALS training as well as those responsible for the medical treatment of cardiac arrest and real end-users (doctors, nurses and porters) helped establish a wide learning space. The extensive exchange of knowledge in the group entailed a profound understanding on the requirements on computerization of the CPG for ALS. During the workshops, new aims for the project were brought up and some of them were agreed upon in the steering group. For example, it was agreed as a requirement that it should

be possible to use the artifact for calculation of the correct medication dosage for children. Further, the involvement of actors doing research on handling of cardiac arrest implied an extension of the requirements to include the possibility of real time documentation of actions. Based on the findings in the observations and the workshops, it was clear that the hardware to be applied had to be very robust and easy to interact with for all the actors, as it was clear to all in the design team that ALS could occur ubiquitously at any time. Together, this placed high demands on integration of the design of the application, hardware and user interaction.

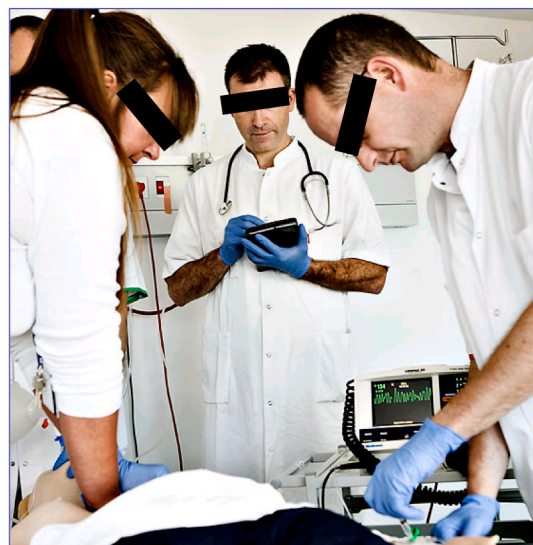
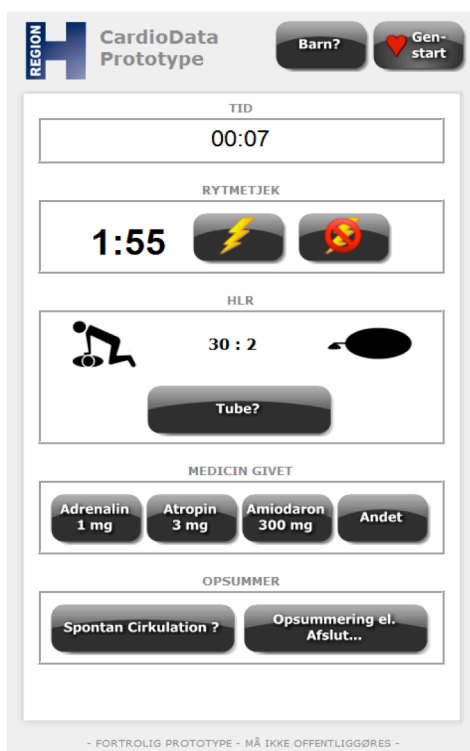


Figure II The user interface of CardioData, and the prototype in use during ALS training in a simulated context

The final design solution (shown in **Error! Reference source not found.**) was an Ultra Mobile PC with touch screen, and a dedicated simple user interface, so the artifact would be easy to interact with during the stressful working conditions while performing ALS. The CardioData device supports the frequency of time intervals between checks of spontaneous cardiac rhythm as well as compression and ventilation frequency as this was observed to constitute a major problem to apply with the ALS CPG on these issues. Further, the solution supports calculation of medication for children and documentation of various standard procedures and medications. When resuscitation is terminated, it is possible to send the collected data to a database, for example to the local electronic health record. The design prototype has been used for training purposes over a period and a project has been established for sophistication of the solution into a product that can be used in clinical practice.

Evaluation of the design process. It was clear that various stakeholders had various agendas. The requirement for collecting data for scientific purposes came from medical researchers, and the requirement for feedback came from those responsible for the training, while the end-users in the cardio team were focusing on interaction and robustness. The diversity of interests was negotiated both in workshops and in the steering group. We found it very helpful to include both technicians and health professionals in both groups, with the two informatician students with a health professional background serving as process facilitators. We are convinced that the features and functionality of the running prototype reach far beyond what we would have come up with if the computerization of the ALS CPG had been made purely based on a CPG-document analysis and requirements from the ALS trainers.

3.1.2 Case B: The oncology case

The aim of this project was to examine current use of CPGs and the potential implications for computerization within oncology, and to come up with a pilot computerization of a CPG. The oncology specialty was chosen as it is known that protocols and CPGs are widely used and complied with within this specialty [54]. The project took place within three oncology clinics in the Copenhagen Region (two situated at university hospitals and one in a large regional hospital). Focus in the project was on application of protocols in clinical work practice. Protocols are a special type of CPGs, providing recommendations for a specific cure for a specific disease. Most protocols include a standard patient pathway for the disease in case. Close to all patients within the oncology clinics examined were treated according to a protocol: 20-25% of the patients were treated according to a research protocol, the rest according to a standard treatment protocol. Each of the three clinics in the project had between 50 - 110 protocols in use at any time. Most of the protocols were in use in more than one of the clinics.

The philosophy behind the design project: This project was initiated as a research project by university researchers, as part of a bigger research project on clinical process support. The aim was to engage local health professionals in the project and in that way establish ownership to the project within the hospitals. It was however not possible to establish a proper steering committee, it was only possible to appoint contact persons in each of the three clinics, implying a compromised ownership. Both nurses and physicians in the oncology clinics were participating in design workshops being specialist in each their part of the clinical work practice. It was a business strategic aim that the solution should support clinical safety and compliance with the CPG in the clinical setting as part of clinical process support. The time frame for this project was ten months. The first three months were used on observation studies and analysis of findings

The applied tools and techniques: A physician and an anthropologist made observations in each of the three clinics taking part in the project. The observations were supplemented with ad-hoc interviews with health professionals and secretaries in the clinics. Further, the currently applied CPG remedies; local adaptations of guidance transformed into activity specific forms (conceptualized as second order guiding artifacts) were collected [55]. The findings were analyzed applying a Grounded Theory approach [56]. The results of the primary analysis were presented at staff meetings in each of the clinics. Based on the feedback, a rich picture of a single activity (the ordering, preparation and administration of chemotherapy) was made and discussed with the contact persons. Based on their feedback, a prototype for the activity was developed (presented in [57]. The prototype was applied to initiate discussions at future workshops held in two of the clinics.

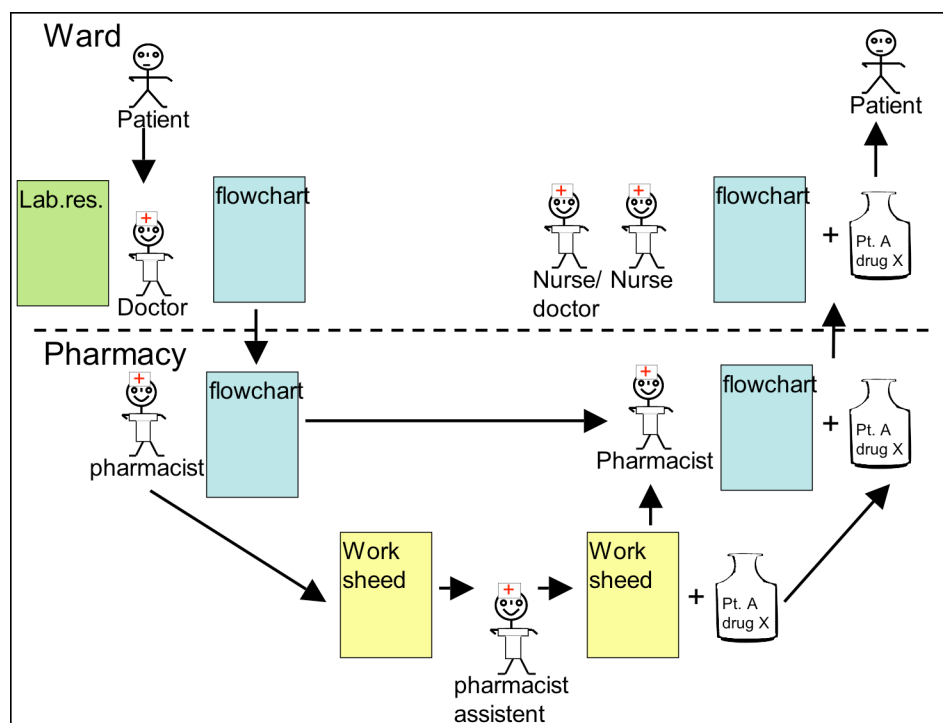


Figure III Rich picture of the ordering, preparation and administration of chemotherapy activity, used in the design process.

The realm of understanding: The close interaction with the health professionals during observations, interviews, clinic presentations and workshops helped establish an understanding of work practice and business strategy. For example re-scheduling of patient pathways were observed to occur frequently and also pointed out by the health professionals as a task they would expect a computerized CPG solution to support. Further, safety in all steps of the ordering, preparation and administration of chemotherapy sequence were pointed out as a key business strategic aim in the workshops. During the observations, it was found that the work practice was

characterized as being ephemeral with frequent handovers between health professionals and use of information from several information systems holding patient data. To support the clinical work practice, the clinics had developed a set of forms (second order guiding artifacts). In the second order guiding artifact, the guideline recommendations were adapted to local conditions and the presentation transformed from the protocols according to a standard operating procedure [45]. Although the transformation from protocol to second order guiding artifacts was carried out locally, it was generally agreed by the clinicians and the nurses responsible for the transformation process that it would be possible to share forms between clinics as they were based on the same protocols and the clinical work practice was standardized. During the future workshops with the health professionals it was made clear that it was a mandatory requirement that a future computerization of CPGs should fulfill most of the functionality and characteristics of the comprehensively applied second order guiding artifacts. The second order guiding artifacts that had been developed over decades in close interaction with the users served as a frame of reference for all the users in our study.

The final design solution was a simple web-based workflow for the ordering, preparation and administration of chemotherapy in a commercial workflow engine [55]. It was agreed at the workshops that this was an appropriate part of the protocols to computerize, although it was concurrently stated as a mandatory requirement that the relevant conditional patient data should be presented simultaneously. Thus, further development in the project has been postponed as it is realized that the currently ongoing implementation of a new CPOE and an electronic patient record system constitutes a basic foundation for the computerization of the CPGs within the oncology clinics.

Evaluation of the design process: In this project, the developed prototype was used to initiate discussions in workshops and for design laboratory experiments. The researchers found a substantial interest in computerization of protocols among the involved clinicians. It was however a problem that a profound ownership to the project was not established in the clinics. A reason for this was the coincidence with implementation of two major information systems within the hospitals that consumed most of the resources the clinics were able to set aside for taking part in IT-development projects. On the other hand, during our design project, the implementation of these systems was disclosed as a basic foundation for computerization of CPGs beyond basic presentation. Thus, the next step in the design of computerized protocols for oncology has been postponed until the CPOE and the record system is implemented.

4 Discussion

Applying a PD approach can help disclose contextual requirements for the design of computerized CPGs. This was illustrated in the two cases, where comprehensive and rather diverse requirements originating from work practice and business strategy were disclosed. These requirements would not have been disclosed if the computerization had been designed purely based on an analysis of the intrinsic CPG requirements, as is the cases in most current publications of CPG computerization [14, 19, 20].

The impact of the design approach on the final solution

Decisions on which design approach to apply for computerization of CPGs has to be made as one of the first steps when setting up a CPG computerization project. Application of a PD approach will influence all subsequent decisions and actions in the project [24]. A PD approach reaches far beyond a traditional software development approach where the focus of attention is primarily on the technology [35]. In 'traditional' software approaches, the IT designers' achievement of a thorough understanding of the work practice is often assigned a minor role, as the approach is based on the assumption that requirements should be formulated in terms of technical challenges, and that requirements can formalize work as routine [58]. These 'traditional' assumptions are in profound contrast to the philosophic foundations for PD, where establishing requirements based on active involvement of users from the domain and IT-designers' firsthand experience of work practice, are regarded as essentials for an efficient design process that leads to functional solutions that can be applied in practice [24, 59].

Clinical work is known to be complex and ephemeral [12, 60]. Therefore, clinical work practice in itself can be expected to place substantial demands on the design of computerized CPGs. Further, CPG recommendations often have to be executed in a flexible way that is tailored to the individual patient based on an assessment of the clinical examination and existing patient data [2]. These issues have to be taken into account while designing computerized CPGs [61]. The two cases illustrate that although the CPG recommendations in both cases could be presented in rather simple workflow algorithms, the PD approach lead to major differences as to the emergence of requirements for computerized CPGs due to differences in clinical work practice and business strategy. In the ALS case were several actors are working concurrently on the treatment of a patient under extreme time pressure, there was no need for access to existing data, but the working conditions entailed demands on the design of a robust solution with a simple user interface. In the oncology case, we experienced comprehensive requirements for access to existing patient data and for tools supporting re-scheduling of the individual patient's CPG-based

clinical pathway, as this was frequently called for. None of these detailed requirements would have been brought forward if we had just made an analysis of the intrinsic CPG requirements.

How can PD contribute to improved application of CPGs in clinical practice?

Implementation of CPGs is situated in the middle of a fundamental conflict between professionals with highly standardized professional skills trained to have control over their own work and deterministic governance trying to standardize work procedures [5]. There is no simple solution to this complex problem, which is why a multifaceted CPG implementation approach is recommended [10]. Numerous factors influence CPG compliance, some are related to the content of the CPGs, some to the presentation of the CPGs while others are related to the users and the field of application [6, 62, 63]. Computerization of CPGs needs to address all four factors. Providing computer access to CPGs in itself only lead to slightly improved compliance with CPGs [64]. Applying a PD approach while computerizing CPGs holds the potential of bringing CPG compliance yet one step further, because PD provides tools and techniques for taking the norms and values of the target users as well as the characteristics of the field of application into account. Taking these areas of concern into account are recommended as part of a multifaceted implementation strategy [62]

CPG recommendations have to be executed within a specific organizational context, therefore they have to be adapted to local work practice as part of implementation [45]. Further, the introduction of a new clinical practice and/or new technology may entail new ways of organizing the work practice [12]. A PD approach provides an arena for the stakeholders to present and discuss various viewpoints on adaptation of CPGs, on technology to support the application and on desired future work practice. Clinicians may worry about support for smooth cooperation practices, unit managers about efficient deployment of resources, quality managers about how to ensure the certification or accreditation of the organization while the IT-designers worry about optimal exploitation of technological artifacts [2]. Further, the juniors and seniors in the field may not have the same needs for guidance. These issues are to be negotiated, balanced and prioritized, and PD may facilitate such a process. The various PD tools and techniques help obtain knowledge about problem areas. The knowledge is applied for creating a shared realm of understanding. This in turn provides the foundation for an arena where various viewpoints and requirements can be negotiated and prioritized openly and related to business strategic decisions. The process supports disclosing of requirements for the design solution while at the same time establishing ownership in the organization. Thus, applying a PD approach for the design of computerized CPGs can help design

solutions where all factors mentioned above are being taken into account, thereby facilitating CPG compliance in practice.

In our two cases, the issue of how PD can contribute to improved application of CPGs in clinical practice can be illustrated by some of the key decisions made in the projects: In the ALS case it was decided that a substantial part of the user interface should be used for a clock counting down in two-minute intervals and a rhythm indicator as the observation studies revealed that the CPG recommendations regarding time intervals and cardiac compression rhythm were the most difficult to comply with. Therefore, a business strategic decision was made that it was the two most important areas to address in the design in order to obtain improved CPG compliance. In the oncology case, the observation study and interviews revealed that recommended patient pathways frequently had to be modified or even rescheduled either due to adverse effects of treatment or due to other (external) reasons. Therefore, a business strategic decision was made that the solution should facilitate the alteration of patient pathways within the framework of the CPG recommendations.

What are the potential benefits and disadvantages of PD for computerized CPGs?

Applying a PD approach while computerizing CPGs implies that the stakeholders have an arena where they can express their needs and requirements to the implementation of CPGs and the design of the computer artifact. Further, PD provides tools and techniques that help reveal requirements both regarding the level of granularity of guidance as well as on clinical monitoring/documentation, as these two issues are profoundly interrelated [65]. The PD approach, however, increases the complexity in the design process as numerous requirements related to the implementation and application of CPGs in a clinical work practice and from business strategic decisions are displayed. Despite this we find that it is beneficial to involve users in the design of computerized CPGs. The benefits include process benefits, such as speedy creation of a requirement specification and establishment of ownership of the solution within the organization [24], as well as product benefits such as a good match between user needs and the final solution [66].

In PD, end-users are regarded as experts on their work practice, this could be perceived as potentially in conflict with CPG dissemination, as the aim of CPGs are to provide a guide on recommended best clinical practice [8]. However, one has to distinguish between the medical work practice that is addressed by CPGs and the organizational work practice that has evolved locally on which the local work force are the experts. The medical and the organizational work practice influence each other and will both have an influence on and be influenced by computerization of

CPGs [12]. The distinction in medical and organizational work practice has to be taken into account in the PD process.

When applying a PD approach, one has to be aware of the interpersonal relations, as most of the tools and techniques entail active interpersonal interaction not only between users and IT-designers but also among users. The interaction among users will often reflect their individual or organizational power base [67]. A single CPG may hold recommendations that affect several users from various professions and specialties, thus, it is relevant to ensure that the users engaged in the design process have competencies regarding all relevant details of the work affected by the CPG. Both power bases and scope of work practice knowledge have to be addressed while selecting users for a design project.

Ideally, users should be fully-fledged members of the design team, all having power to influence decisions [39]. Are the users jointly taking part in designing the CPG computerization or are they merely validating the design solutions? The balance may rely on who initiated the project and who is sponsoring the project [68]. However, this is not to argue that the users always have to be involved in all parts of the design process. The participation has to be on a realistic level that matches the aim of the project and the resources that can be set aside for organizational development, although it must be on a level that provide the users with an experience of genuine influence on the final solution [39]. User involvement in the design process will always be a trade off between the expected outcome and the time and competences invested in the design project.

Establishment of constructive cooperation based on a shared understanding requires open communication, where the participants apply a shared language [51]. In our two cases, we found it beneficial to include facilitators with a dual education as health professionals and informaticians, serving as liaisons translating clinical terms and basic clinical assumptions into common language that could be understood by the rest of the design team members. Further, it is known from examination of product design that end-users may not be fully aware of their needs, or they may not be able to articulate their needs [69]. One should therefore be aware that the PD tools and techniques applied should be selected to compensate for any such shortcomings. Here, we have found that rich pictures, role-plays and mock-ups have helped to liberate user ideas.

The issue of designing a solution for a specific work setting or focusing on a general-purpose solution has to be discussed during the planning of the design project. There is a general trend on standardization of clinical work based on CPGs in the healthcare sector [2], that could support the idea of general purpose design. On the other hand, this is contradicted by the basic assumption claiming that there will always be local demands on the design of technology for

support of work [24]. We have shown how PD offers guidance as to how to handle this paradox lies in a discussion on the level of detail in the presentation of guidance. The more detailed the guidance on how the clinical work practice for specific activities should be organized the more the solution have to be fitted to a specific local setting. Conversely, the less detailed the guidance on organizational issues the more generic the solution can be.

5 Conclusion

Based on a review of PD literature and as illustrated by our two cases, we find that a PD approach increases the apparent complexity of the design of computerized CPGs as numerous requirements related to the application of CPGs in clinical work practice and to the business strategy are displayed. Despite this, we find that the benefits of PD with active involvement of users in the design process exceed the disadvantages. The most prominent benefit of a PD approach is efficient inclusion of contextual requirements in the design and thereby improved functionality of the final solution in practice [34]. Further, the delegation of power to ordinary users in the design process helps establish ownership in the organization and thereby facilitates implementation [24].

PD provides tools and techniques for a design process where technology, CPG, existing work practice and business strategy are adapted and matched in an orchestrated way. Of course we do not claim that PD will be a panacea to solve all problems, but it can provide a solid basis for the design of computerized CPGs.

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